Official Journal of the European Union

L 423

English edition

Legislation

Volume 63

15 December 2020

Contents

II *Non-legislative acts*

REGULATIONS

★ **Commission Implementing Regulation (EU) 2020/2079 of 8 December 2020 approving amendments to the product specification for a spirit drink whose name is registered as a geographical indication (Münchener Kümmel)** 1

★ **Commission Implementing Regulation (EU) 2020/2080 of 9 December 2020 concerning the classification of certain goods in the Combined Nomenclature** 3

★ **Commission Regulation (EU) 2020/2081 of 14 December 2020 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards substances in tattoo inks or permanent make-up** [1] 6

★ **Commission Implementing Regulation (EU) 2020/2082 of 14 December 2020 on setting the weighted average of maximum mobile termination rates across the Union and repealing Implementing Regulation (EU) 2019/2116** 18

★ **Commission Implementing Regulation (EU) 2020/2083 of 14 December 2020 amending Annex I to Regulation (EC) No 798/2008 as regards the entry for Japan in the list of third countries, territories, zones or compartments from which certain poultry commodities may be imported into or transit through the Union in relation to highly pathogenic avian influenza** [1] 20

★ **Commission Implementing Regulation (EU) 2020/2084 of 14 December 2020 amending and correcting Implementing Regulation (EU) 2018/2067 on the verification of data and on the accreditation of verifiers pursuant to Directive 2003/87/EC of the European Parliament and of the Council** [1] 23

★ **Commission Implementing Regulation (EU) 2020/2085 of 14 December 2020 amending and correcting Implementing Regulation (EU) 2018/2066 on the monitoring and reporting of greenhouse gas emissions pursuant to Directive 2003/87/EC of the European Parliament and of the Council** [1] 37

[1] Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

★ **Commission Implementing Regulation (EU) 2020/2086 of 14 December 2020 amending Implementing Regulation (EU) 2020/532 as regards a derogation from Implementing Regulation (EU) No 809/2014 for checks by monitoring relating to aid applications for area-related aid schemes and payment claims for area-related support measures** 48

★ **Commission Implementing Regulation (EU) 2020/2087 of 14 December 2020 concerning the non-renewal of the approval of the active substance mancozeb, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011** [1] 50

DIRECTIVES

★ **Commission Directive (EU) 2020/2088 of 11 December 2020 amending Annex II to Directive 2009/48/EC of the European Parliament and of the Council as regards the labelling of allergenic fragrances in toys** [1] 53

★ **Commission Directive (EU) 2020/2089 of 11 December 2020 amending Annex II to Directive 2009/48/EC of the European Parliament and of the Council as regards the prohibition of allergenic fragrances in toys** [1] 58

DECISIONS

★ **Decision (EU) 2020/2090 of the European Central Bank of 4 December 2020 amending Decision ECB/2013/10 on the denominations, specifications, reproduction, exchange and withdrawal of euro banknotes (ECB/2020/60)** 62

GUIDELINES

★ **Guideline (EU) 2020/2091 of the European Central Bank of 4 December 2020 amending Guideline ECB/2003/5 on the enforcement of measures to counter non-compliant reproductions of euro banknotes and on the exchange and withdrawal of euro banknotes (ECB/2020/61)** 65

[1] Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2020/2079

of 8 December 2020

approving amendments to the product specification for a spirit drink whose name is registered as a geographical indication (Münchener Kümmel)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2019/787 of the European Parliament and of the Council of 17 April 2019 on the definition, description, presentation and labelling of spirit drinks, the use of the names of spirit drinks in the presentation and labelling of other foodstuffs, the protection of geographical indications for spirit drinks, the use of ethyl alcohol and distillates of agricultural origin in alcoholic beverages, and repealing Regulation (EC) No 110/2008 ([1]), and in particular Article 30(2) thereof,

Whereas:

(1) Pursuant to Article 21 in conjunction with Article 17(5) of Regulation (EC) No 110/2008 of the European Parliament and of the Council ([2]), the Commission has examined Germany's application of 28 September 2017 for the approval of amendments to the technical file for the geographical indication 'Münchener Kümmel', protected under that Regulation. The amendments include changing the name 'Münchener Kümmel' to 'Münchener Kümmel'/ 'Münchner Kümmel'.

(2) Regulation (EU) 2019/787, which replaces Regulation (EC) No 110/2008, entered into force on 25 May 2019. Under Article 49(1) thereof, Chapter III of Regulation (EC) No 110/2008 on geographical indications is repealed with effect from 8 June 2019. Under Article 22(2) of Regulation (EU) 2019/787, technical files submitted as part of any application before 8 June 2019 under Regulation (EC) No 110/2008 shall be deemed to be product specifications.

(3) After concluding that the application complied with Regulation (EC) No 110/2008, the Commission published the amendment application in the *Official Journal of the European Union* ([3]) as required by Article 17(6) of that Regulation, in accordance with the first subparagraph of Article 50(4) of Regulation (EU) 2019/787.

(4) As no notice of opposition under Article 27(1) of Regulation (EU) 2019/787 has been received by the Commission, the amendments to the specification should be approved pursuant to Article 30(2) of that Regulation, which applies *mutatis mutandis* to product specification amendments,

([1]) OJ L 130, 17.5.2019, p. 1.

([2]) Regulation (EC) No 110/2008 of the European Parliament and of the Council of 15 January 2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89 (OJ L 39, 13.2.2008, p. 16).

([3]) OJ C 254, 3.8.2020, p. 21.

HAS ADOPTED THIS REGULATION:

Article 1

The amendments to the specification for the name 'Münchener Kümmel', published in the *Official Journal of the European Union*, are hereby approved.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 8 December 2020.

For the Commission,
On behalf of the President,
Janusz WOJCIECHOWSKI
Member of the Commission

COMMISSION IMPLEMENTING REGULATION (EU) 2020/2080

of 9 December 2020

concerning the classification of certain goods in the Combined Nomenclature

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code ([1]), and in particular Article 57(4) and Article 58(2) thereof,

Whereas:

(1) In order to ensure uniform application of the Combined Nomenclature annexed to Council Regulation (EEC) No 2658/87 ([2]), it is necessary to adopt measures concerning the classification of the goods referred to in the Annex to this Regulation.

(2) Regulation (EEC) No 2658/87 has laid down the general rules for the interpretation of the Combined Nomenclature. Those rules apply also to any other nomenclature which is wholly or partly based on it or which adds any additional subdivision to it and which is established by specific provisions of the Union, with a view to the application of tariff and other measures relating to trade in goods.

(3) Pursuant to those general rules, the goods described in column (1) of the table set out in the Annex should be classified under the CN code indicated in column (2), by virtue of the reasons set out in column (3) of that table.

(4) It is appropriate to provide that binding tariff information issued in respect of the goods concerned by this Regulation which does not conform to this Regulation may, for a certain period, continue to be invoked by the holder in accordance with Article 34(9) of Regulation (EU) No 952/2013. That period should be set at three months.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

Article 1

The goods described in column (1) of the table set out in the Annex shall be classified within the Combined Nomenclature under the CN code indicated in column (2) of that table.

Article 2

Binding tariff information which does not conform to this Regulation may continue to be invoked in accordance with Article 34(9) of Regulation (EU) No 952/2013 for a period of three months from the date of entry into force of this Regulation.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

([1]) OJ L 269, 10.10.2013, p. 1.

([2]) Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 9 December 2020.

For the Commission,
On behalf of the President,
Gerassimos THOMAS
Director-General
Directorate-General for Taxation and Customs Union

ANNEX

Description of the goods	Classification (CN code)	Reasons
(1)	(2)	(3)
Salted and dried tomato halves, suitable for immediate consumption. The salt content ranges from 10,65 % to 17,35 % by weight. According to the different levels of salt content, the product is subdivided into different quality categories, serving different uses. The production process consists of cutting fresh tomatoes, salting them and subsequently exposing them to the sun for drying. The main function of salting is seasoning and establishing different quality categories. As a subsidiary effect, salting speeds up the drying and preserves the product. The product is put up in vacuum packs of different sizes in cardboard boxes, stored at a temperature of less than 5 °C.	2002 10 90	Classification is determined by general rules 1 and 6 for the interpretation of the Combined Nomenclature and the wording of CN codes 2002, 2002 10 and 2002 10 90. Heading 0711 covers vegetables which have been treated solely to ensure their provisional preservation during transport or storage prior to use, provided they remain unsuitable for immediate consumption in that state. As the product at issue is suitable for immediate consumption, classification under heading 0711 is excluded. Heading 0712 covers dried vegetables which have not undergone further preparation. Salting is not a process provided for in Chapter 7. It is considered as a further preparation because drying processes do not necessarily require the addition of salt. Consequently, classification under heading 0712 is excluded. The product is therefore to be classified under CN code 2002 10 90 as tomatoes prepared or preserved otherwise than by vinegar or acetic acid.

COMMISSION REGULATION (EU) 2020/2081

of 14 December 2020

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards substances in tattoo inks or permanent make-up

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC ([1]), and in particular Article 68(1) thereof,

Whereas:

(1) Annex XVII to Regulation (EC) No 1907/2006 lays down restrictions on the manufacture, placing on the market and use of certain substances on their own, in mixtures or in articles.

(2) The number of people in the Union with tattoos or permanent make-up has been increasing steadily, in particular in the young population. The procedures used for tattooing or permanent make-up (referred to collectively as 'tattooing'), whether involving the use of needles or the application of some other technique such as micro-blading, inevitably cause an injury to the skin barrier. As a result, the inks or other mixtures used for tattooing are absorbed into the body. Mixtures used for tattooing generally consist of colorants and auxiliary ingredients such as solvents, stabilisers, wetting agents, pH regulators, emollients, preservatives and thickeners. The mixtures are introduced into the human skin, inside the eyeball or into mucous membranes. The colorants mostly remain close to where the mixture is administered, so that the tattoo or permanent make-up will remain visible. However, the soluble ingredients in the mixture are distributed within a matter of hours or days across the entire body. In consequence, the skin and other organs are exposed to the effects of those soluble substances over an extended period. Some of those substances have hazardous properties that pose a potential risk to human health. In addition, metabolism of the colorants in the skin, decomposition due to solar radiation exposure and laser irradiation may also lead to the release of hazardous chemicals from the area of the body where the tattoo or permanent make-up is located ([2]).

(3) Mixtures placed on the market for use for tattooing purposes are products falling within the scope of Directive 2001/95/EC of the European Parliament and of the Council ([3]). Directive 2001/95/EC allows producers to place products on the market only if they are safe. Member States enforce this obligation by taking actions in respect of dangerous products on the market and notifying those actions to the Commission through the Community Rapid Information System (RAPEX). RAPEX notifications on chemicals contained in mixtures used for tattooing purposes have been increasing in recent years ([4]).

(4) In 2003, the Council of Europe adopted resolution ResAP (2003)2 ([5]) on the safety of tattoos and permanent make-up. That resolution was superseded in 2008 by resolution ResAP (2008)1 ([6]). The 2008 resolution recommended a number of provisions relating to tattooing practices and the chemical composition of mixtures for tattooing purposes to ensure that they do not endanger the health and safety of the public.

([1]) OJ L 396, 30.12.2006, p. 1.

([2]) JRC Science for Policy report Safety of tattoos and permanent make-up: Final report, 2016 https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/safety-tattoos-and-permanent-make-final-report

([3]) Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.1.2002, p. 4).

([4]) https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/index_en.htm

([5]) Council of Europe Resolution ResAP (2003)2 on tattoos and permanent make-up, adopted by the Committee of Ministers on 19 June 2003 at the 844th meeting of the Ministers' Deputies- http://www.ctl-tattoo.net/Documents/PDF/eu_resap_2003_2.pdf

([6]) Council of Europe Resolution ResAP(2008)1 on requirements and criteria for the safety of tattoos and permanent make-up (superseding Resolution ResAP(2003)2 on tattoos and permanent make-up), adopted by the Committee of Ministers on 20 February 2008 at the 1018th meeting of the Ministers' Deputies - https://rm.coe.int/16805d3dc4

(5) Based on the Council of Europe recommendations, seven Member States put national legislation in place regulating the chemical composition of mixtures for tattooing purposes ([7]).

(6) On 12 March 2015, the Commission asked the European Chemicals Agency ('the Agency') pursuant to Article 69(1) of Regulation (EC) No 1907/2006 to prepare a dossier in order to assess the risks to human health of certain chemicals contained in mixtures used for tattooing purposes, and the need for Union-wide action beyond the national measures already in place in some Member States and beyond the measures based on the general safety requirements laid down in Directive 2001/95/EC. The dossier prepared by the Agency in response to the Commission's request is referred to in this Regulation as 'the Annex XV dossier'.

(7) The Agency prepared the Annex XV dossier in cooperation with Italy, Denmark and Norway (the Agency and Italy, Denmark and Norway are together referred to as 'the dossier submitters') and with the assistance of the German Federal Institute for Risk Assessment and the German Federal Institute for Occupational Health and Safety. On 6 October 2017, the dossier submitters submitted the Annex XV dossier ([8]). The dossier demonstrated that the risks to human health due to exposure to certain hazardous chemicals in mixtures used for tattooing purposes are not adequately controlled and need to be addressed on a Union-wide basis to achieve a harmonised high level of protection to human health and free movement of goods within the Union.

(8) The Annex XV dossier proposed a restriction prohibiting both the placing on the market of mixtures for use for tattooing purposes and the use of mixtures for tattooing purposes if they contained any substances classified under Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([9]) in the hazard classes carcinogenicity, mutagenicity or toxicity to reproduction category 1A, 1B or 2, skin sensitisation category 1, 1A or 1 B, skin corrosion category 1, 1A, 1B, 1C or skin irritation category 2, or serious eye damage category 1 or eye irritation category 2. The Annex XV dossier also proposed the inclusion of certain substances listed in Annex II or IV to Regulation (EC) No 1223/2009 of the European Parliament and of the Council ([10]) with specific conditions, and substances listed in Table 1 of the Council of Europe resolution ResAP(2008)1 based on the fact that they may either undergo decomposition to or contain residual aromatic amines classified for carcinogenicity or mutagenicity. The Annex XV dossier proposed to exclude from the restriction substances that were classified in the hazard classes carcinogenicity or mutagenicity category 1A, 1B or 2 due to effects following exposure by inhalation only and not through any other route such as dermal or oral.

(9) In addition, the Annex XV dossier proposed a number of labelling requirements, some of them modified following advice from the Agency's Forum for Exchange of Information on Enforcement ('the Forum') during the opinion development process. The labelling requirements proposed in the Annex XV dossier included a requirement to state the fact that the mixture was for use for tattooing purposes, a requirement to specify a unique reference number for identifying the specific batch, a requirement to list any ingredients classified as hazardous to human health in Part 3 of Annex VI to Regulation (EC) No 1272/2008 but not covered by the proposed restriction, and any ingredients covered by the proposed restriction but used in the mixture below the concentration limit set by the proposed restriction. Furthermore, an additional labelling requirement to indicate the presence of nickel and chromium (VI) was considered necessary, as these particular substances can induce new cases of skin sensitisation and potentially trigger allergic reactions in sensitised persons. The labelling requirements were proposed in order to give consumers and tattooists additional information, to facilitate implementation of the restriction, and to ensure that investigations can be properly carried out in the event of adverse health effects.

(10) The Annex XV dossier set out two possible restriction options (RO1 and RO2), each with different concentration limits for the substances falling within the scope of the restriction. RO1 contained lower concentration limits than RO2. The two options also contained alternative approaches for handling future updates to Annexes II and IV to Regulation (EC) No 1223/2009. RO1 suggested to apply the restriction not only to substances currently listed in those Annexes (with the requisite conditions), but also to substances listed in those Annexes at any time in the future. In other words, the restriction would apply to those substances automatically without the need to start a further restriction process or to amend Annex XVII to Regulation (EC) No 1907/2006 again. This approach is referred to as 'dynamic'. RO2 suggested to apply the restriction only to substances currently listed in those Annexes

([7]) Belgium, France, Germany, the Netherlands, Slovenia, Spain and Sweden.

([8]) Annex XV restriction report-proposal for a restriction: substances in tattoo inks and permanent make up- October 2017-ECHA with Denmark, Italy and Norway-https://echa.europa.eu/documents/10162/6f739150-39db-7e2c-d07d-caf8fb81d153

([9]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

([10]) Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).

(with the requisite conditions). This approach is referred to as 'static'. Both options RO1 and RO2 proposed a 'dynamic' restriction for substances classified under Regulation (EC) No 1272/2008. This was on the grounds that it was necessary to ensure a sufficient level of protection against the human health risks posed by the presence of substances in mixtures used for tattooing purposes that are classified in the relevant categories under that Regulation.

(11) On 20 November 2018, the Agency's Committee for Risk Assessment (RAC) adopted an opinion concluding that the proposed restriction, with certain modifications proposed by RAC, was the most appropriate Union-wide measure to address the identified risk arising from the various substances in question, in terms of both effectiveness in reducing the risk, practicability and monitorability.

(12) RAC considered that all relevant health hazard classes were covered by the Annex XV dossier and agreed with the hazard assessment for the substances and group of substances. In addition to the restriction options proposed under RO1 and RO2, RAC proposed a modified version of the RO1 concentration limits. RAC considered these modifications necessary because the concentration limits for some substances in RO1 and RO2 did not provide sufficient protection. For other substances, more practicable concentration limits could be proposed, in RAC's view, while still minimising the risk for human health.

(13) RAC did not agree with the proposal to exclude two primary aromatic amines listed in Table 1 of the ResAP (2008)1 from the scope of the proposed restriction, namely 6-amino-2-ethoxynaphthaline (CAS No 293733-21-8) and 2,4-xylidine (EC No 202-440-0; CAS No 95-68-1).

(14) However, RAC agreed with the dossier submitters' proposal to exclude carcinogenic and mutagenic substances of category 1A, 1B or 2 that present this hazard due to effects following exposure by inhalation only. RAC considered that substances presenting such a hazard due to effects following exposure by inhalation only were not relevant in the case of intradermal exposure to mixtures used for tattooing purposes. In addition, RAC supported the modification put forward by the dossier submitters in response to advice given by the Forum during the opinion-making process. The Forum proposed to exempt substances that are gases at standard temperature and pressure, since they are not expected to be found in mixtures used for tattooing purposes due to their physical state. The only exception would be formaldehyde since the public consultation indicated that formaldehyde can be found in tattoo inks in a dissolved state. RAC also agreed that risks of exposure by tattoo artists to mixtures administered by them for tattooing purposes are out of the scope of the Annex XV dossier.

(15) RAC did not support the dossier submitters' proposal for exclusion from the scope of the restriction of 21 colorants (19 non-phthalocyanine and 2 phthalocyanine pigments). Those colorants are banned by Annex II to Regulation (EC) No 1223/2009 for use in hair colours. However, the blue phthalocyanine colorant (Pigment Blue 15:3) is allowed by Annex IV to that Regulation for use in other cosmetic products while the green phthalocyanine colorant (Pigment Green 7) is allowed for other cosmetic products other than eye products. RAC considered that the risk of cancer and possible non-carcinogenic hazards could not be ruled out for the majority of these colorants, primarily due to the lack of adequate information on their hazard properties and on the risk for human health. Moreover, RAC noted that during the public consultation stakeholders pointed out that only two of these colorants, namely the two phthalocyanine-based colorants Pigment Blue 15:3 and Pigment Green 7, were essential for tattooing on account of the fact that there were no safer and technically adequate alternatives available for them.

(16) RAC supported a dynamic link with both Regulation (EC) No 1223/2009 and Regulation (EC) No 1272/2008 as such links provide greater protection for human health.

(17) RAC agreed with the dossier submitters that, as regards the date when the new restriction should begin to apply, a transitional period of 12 months would allow sufficient time for actors in the supply chain to meet the new requirements.

(18) On 15 March 2019, the Agency's Committee for Socioeconomic Analysis (SEAC) adopted an opinion, indicating that the proposed restriction, with the modifications proposed by RAC and SEAC, was the most appropriate Union-wide measure to address the identified risks in terms of its socioeconomic benefits and socioeconomic costs. SEAC reached that conclusion based on the best available information, taking into account that the significant benefits to society, in terms of the adverse skin effects and other health impacts that would be avoided, were likely to be higher than the compliance costs for industry. Moreover, SEAC concluded that the restriction would not have a significant negative economic impact on the supply chains affected, that it would be affordable in terms of price increases to consumers and that the restriction would minimise risks of regrettable substitution.

(19) SEAC agreed with the conclusions in the Annex XV dossier and with RAC that a transitional period of 12 months seemed reasonable and sufficient to enable actors involved in the supply chains to comply with the restriction.

(20) SEAC also supported creating a dynamic link with Regulation (EC) No 1272/2008 that would take into account any future changes to the classification of substances listed in Part 3 of Annex VI of that Regulation on the grounds that it would produce human health benefits more quickly. With regard to future changes to Annex II or Annex IV to Regulation (EC) No 1223/2009, SEAC expressed a slight preference for a static link. In SEAC's opinion, although a static link may result in a delay in achieving the health benefits provided by the restriction, it would allow for a proper scientific scrutiny of the concentration limits appropriate for the specific use of the substances in tattooing procedures, and also for a proper assessment of the availability of alternatives.

(21) SEAC agreed with RAC that it was appropriate to restrict the 19 colorants banned in cosmetic products as, according to the information available, some are not currently used for tattooing purposes and there are alternatives available. However, for Pigment Blue 15:3 and Pigment Green 7, comments raised during the public consultation indicated that there were no safer and technically feasible alternatives available to cover this spectrum of colours. As regards Pigment Green 7, comments indicated that it was largely replaced by the brominated Pigment Green 36 although RAC considered that Pigment Green 36 was not a less hazardous alternative. Therefore, SEAC recommended a time-limited derogation of 36 months for both pigments considering the time needed by manufacturers to reformulate the mixtures. In addition, SEAC supported the exemption for gases at standard temperature and pressure in line with RAC's conclusion that such gases are not expected to be found dissolved in mixtures for tattooing purposes. Based on information from the public consultation SEAC also supported the exclusion of formaldehyde from that exemption.

(22) SEAC supported the inclusion of labelling requirements and recommended the alignment of the labelling requirements with the requirements of Regulation (EC) No 1272/2008, to prevent duplication of information.

(23) The Forum was consulted on the proposed restriction in accordance with Article 77(4)(h) of Regulation (EC) No 1907/2006 and its recommendations have been taken into account.

(24) On 11 June 2019, the Agency submitted the opinions of RAC and SEAC ([11]) to the Commission.

(25) Taking into account the Annex XV dossier and the RAC and SEAC opinions, the Commission considers that there is an unacceptable risk to human health arising from certain substances in mixtures for use for tattooing purposes above specific concentration limits. The Commission also considers that the risk needs to be addressed on a Union-wide basis.

(26) The Commission agrees with RAC and SEAC that, above a certain practical concentration threshold, a wide range of hazardous substances identified for the purposes of Regulation (EC) No 1272/2008, Regulation (EC) No 1223/2009 and Council of Europe resolution ResAP (2008)1 should not be used in tattooing procedures. Moreover, the restriction should also ban the placing on the market of mixtures for use for tattooing purposes if they contain any such substance above the specified practical concentration threshold. By way of an ancillary requirement, suppliers placing mixtures on the market for use for tattooing purposes, within the parameters permitted by the restriction, should be required to provide sufficient information to encourage safe use of their mixtures.

(27) The Commission agrees with RAC and SEAC that the restriction should not apply to carcinogenic and mutagenic substances with harmonised classification due to effects following exposure by inhalation only. The same analysis applies to reproductive toxicants even though no reproductive toxicant is currently classified due to inhalation exposure only. Therefore, reproductive toxicants with harmonised classification due to effects following exposure by inhalation only should also be excluded from the scope of the restriction.

(28) The Commission agrees with RAC and SEAC that the restriction should not apply to gaseous substances other than formaldehyde as they are not expected to be present in that state in mixtures used for tattooing purposes.

(29) The restriction should cover not just substances currently classified in the relevant hazard categories in Part 3 of Annex VI to Regulation (EC) No 1272/2008 but also substances classified in those hazard categories at any point in the future, following an amendment to that Part adding or changing the classification of a substance. Classification under Regulation (EC) No 1272/2008 is based on a careful assessment of the hazard properties of substances. The way that mixtures are administered for tattooing purposes i.e. by introducing them into a part of the body also gives sufficient indications about the potential exposure to these substances. In summary, both the potential hazard (s) of the substances and the way people are exposed to them leads to the conclusion that these substances present a general level of risk to human health that is unacceptable and needs to be addressed by this restriction in accordance with the requirements set out in Title VIII of Regulation (EC) No 1907/2006.

([11]) Compiled version prepared by the ECHA Secretariat of RAC's opinion (adopted 20 November 2018) and SEAC's opinion (adopted 15 March 2019) https://echa.europa.eu/documents/10162/dc3d6ea4-df3f-f53d-eff0-540ff3a5b1a0

(30) For any substance that subsequently comes within the terms of the restriction as a result of a subsequent amendment to Part 3 of Annex VI to Regulation (EC) No 1272/2008, the restriction should begin to apply to that substance when the classification in that Part begins to apply. This is usually 18 months after the substance has been included in Annex VI to that Regulation. The 18-month period will provide sufficient time for formulators to find safer alternatives, in particular in those cases that might otherwise lead to regrettable substitution. It is not necessary to address the availability of alternatives for substances classified in the future, as the need to ensure a high level of protection of human health takes precedence over considerations related to technical and economic feasibility of alternatives as regards substances used in tattoo inks.

(31) Similarly, the restriction should cover not only substances currently listed with the relevant conditions in Annex II or Annex IV to Regulation (EC) No 1223/2009 but also substances listed with any of those conditions at any point in the future, following an amendment to those Annexes listing or changing the listing of a substance. If the substance raises sufficient safety concerns to be restricted in cosmetic products applied on the skin, it must raise at least the same safety concerns when present in mixtures administered for tattooing purposes, which are introduced through the skin into the human body. It is not necessary to address the availability of alternatives for substances falling within the scope of the restriction in the future as the need to protect human health takes precedence over considerations related to technical and economic feasibility of alternatives.

(32) Nevertheless, as regards those substances that subsequently come within the terms of the restriction as a result of a future amendment to Regulation (EC) No 1223/2009, an additional period of time should be allowed, after the relevant amendment takes effect, in order to give formulators time to adapt to the consequences of the substance coming within the terms of the restriction or to find a safer alternative to it. This is because the assessment required before a substance can be listed in Annex II or Annex IV to Regulation (EC) No 1223/2009 does not allow for specific scrutiny of the substance as regards its effects in mixtures placed on the market for use for tattooing purposes. The additional period of time should be set at 18 months after entry into force of the relevant amendment of Annex II or IV to Regulation (EC) No 1223/2009.

(33) RAC recommended a reduced concentration limit of 0,01 % for substances classified in the hazard classes skin or eye irritant, skin corrosive or serious eye damage on the basis that the 0,1 % limit proposed by the dossier submitters did not provide sufficient protection in the case of a mixture administered intradermally. During the SEAC consultation it was highlighted that, for some acids and bases used as pH regulators in tattoo mixtures, a concentration of 0,01 % or lower may not be sufficient to achieve their function of adjusting the pH of the mixture. Acids and bases exhibit their irritant or corrosive properties because of their extreme pH values. However, the irritancy or corrosivity of a mixture containing such acids and bases will depend mostly on the overall pH of the mixture itself, rather than on the pH and concentration level of individual substances within in. In the light of these factors, it is appropriate to specify a concentration limit of 0,1 % for irritant or corrosive substances when they are used as pH regulators.

(34) Currently, labelling requirements for mixtures used for tattooing purposes are not harmonised across the Union. Given the inherent health risks related to substances in tattoo mixtures and the increasing number of people seeking tattoos and permanent make-up, harmonisation of what is written on the packaging is required to ensure proper implementation of the restriction, and thus establish confidence in a Union-wide market of safe products for tattooing purposes, allow essential monitoring and enforcement by authorities, and address and prevent fragmentation of the internal market.

(35) The Commission considers that, to ensure proper implementation of the restriction and permit direct traceability in case of adverse health effects, a mixture placed on the market in the Union for use for tattooing purposes should be marked with a list of substances added during the process of formulation and present in the mixture for use fortattooing purposes. For the same purpose, the tattooist should provide information marked on the packaging, or included in the instructions for use, to the person undergoing the procedure. The requirement to indicate a full list of ingredients serves to address a possible patchwork of national rules, achieve economies of scale for formulators and harness the full benefits of market harmonisation. Moreover, providing such a full list is also necessary to ensure that the restriction of an extensive list of substances is practically enforceable, monitorable, and effective throughout the Union. The common nomenclature proposed will make it possible to identify the substances by using a unique name in all the Member States. This will enable consumers to easily recognize substances which they have been advised to avoid (for example because of allergies).

(36) To complement the full list of ingredients and any potential labelling requirements under Regulation (EC) No 1272/2008, the Commission agrees with RAC and SEAC as regards the other pieces of information that should be marked on mixtures for use for tattooing purposes, in particular the unique batch number, the presence of any nickel and chromium (VI), and further safety information on the packaging or in the instructions of use. The Commission also considers that the presence of pH regulating substances should be specifically marked.

(37) To facilitate compliance of tattooists with this restriction, only mixtures that are marked with the statement 'Mixture for use in tattoos or permanent make-up' should be used for tattooing purposes.

(38) Taking into account the Annex XV dossier, the opinions of RAC and SEAC, the socioeconomic impact and the availability of alternatives, the Commission concludes that the restriction proposed in the Annex XV dossier, with the modifications described, is the most appropriate Union-wide measure to address the risk identified to human health, without imposing a significant burden on suppliers, tattooists or consumers.

(39) Stakeholders should be allowed sufficient time to take appropriate measures to comply with the new restriction. The Commission considers that a period of 12 months is sufficient for laboratories to establish, and gain the necessary experience with, the analytical methods developed or being developed by the Member States and other stakeholders for checking compliance with the restriction.

(40) The Commission agrees with SEAC's recommendation that a longer period should be allowed for Pigment Blue 15:3 and Pigment Green 7 because of the lack of safer and technically adequate alternatives and the time needed by manufacturers to reformulate their mixtures. The Commission considers, that 24 months is sufficient to find safer alternatives and to remove mixtures placed on the market for use for tattooing purposes containing these pigments from the market.

(41) Mixtures placed on the market for use for tattooing purposes are administered for a variety of reasons, including both aesthetic and medical reasons. Such mixtures may fall within the scope of Regulation (EU) 2017/745 of the European Parliament and of the Council ([12]). When placed on the market or used exclusively for medical purposes within the meaning of Regulation (EU) 2017/745, the restriction established by this Regulation should not apply to them. In order to ensure a consistent regulatory approach between Regulations (EU) 2017/745 and (EC) No 1907/2006 and to guarantee a high level of protection of human health, when the placing on the market or use of such mixtures may be for both, medical and non-medical purposes, the specific obligations and requirements laid down in both Regulations should apply cumulatively.

(42) Regulation (EC) No 1907/2006 should therefore be amended accordingly.

(43) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 133(1) of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annex XVII to Regulation (EC) No 1907/2006 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 December 2020.

For the Commission
The President
Ursula VON DER LEYEN

([12]) Regulation (EU) 2017/745 of the European parliament and the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

ANNEX

Annex XVII to Regulation (EC) No 1907/2006 is amended as follows:

(1) the following entry is added:

'75. Substances falling within one or more of the following points: (a) substances classified as any of the following in Part 3 of Annex VI to Regulation (EC) No 1272/2008: — carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, but excluding any such substances classified due to effects only following exposure by inhalation — reproductive toxicant category 1A, 1B or 2 but excluding any such substances classified due to effects only following exposure by inhalation — skin sensitiser category 1, 1A or 1B — skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2 — serious eye damage category 1 or eye irritant category 2 (b) substances listed in Annex II to Regulation (EC) No 1223/2009 of the European Parliament and of the Council (*) (c) substances listed in Annex IV to Regulation (EC) No 1223/2009 for which a condition is specified in at least one of the columns g, h and i of the table in that Annex (d) substances listed in Appendix 13 to this Annex. The ancillary requirements in paragraphs 7 and 8 of column 2 of this entry apply to all mixtures for use for tattooing purposes, whether or not they contain a substance falling within points (a) to (d) of this column of this entry.	1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such substances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or are present in the following circumstances: (a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight; (b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight; (c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitiser category 1, 1A or 1B, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight; (d) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2, or as serious eye damage category 1 or eye irritant category 2, the substance is present in the mixture in a concentration equal to or greater than: (i) 0,1 % by weight, if the substance is used solely as a pH regulator; (ii) 0,01 % by weight, in all other cases; (e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009 (*), the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight; (f) in the case of a substance for which a condition of one or more of the following kinds is specified in column g (Product type, Body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight: (i) "Rinse-off products"; (ii) "Not to be used in products applied on mucous membranes"; (iii) "Not to be used in eye products"; (g) in the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column; (h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix. 2. For the purposes of this entry use of a mixture "for tattooing purposes" means injection or introduction of the mixture into a person's skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as

	permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body. 3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance. 4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023: (a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8); (b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6). 5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification. 6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made. 7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the mixture is marked with the following information: (a) the statement "Mixture for use in tattoos or permanent make-up"; (b) a reference number to uniquely identify the batch; (c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. "Ingredient" means any substance added during the process of formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that ingredient does not need to be marked in accordance with this Regulation;

	(d) the additional statement “pH regulator” for substances falling under point (d)(i) of paragraph 1; (e) the statement ”Contains nickel. Can cause allergic reactions.” if the mixture contains nickel below the concentration limit specified in Appendix 13; (f) the statement ”Contains chromium (VI). Can cause allergic reactions.” if the mixture contains chromium (VI) below the concentration limit specified in Appendix 13; (g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/2008. The information shall be clearly visible, easily legible and marked in a way that is indelible. The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise. Where necessary because of the size of the package, the information listed in the first subparagraph, except for point (a), shall be included instead in the instructions for use. Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this paragraph. 8. Mixtures that do not contain the statement “Mixture for use in tattoos or permanent make-up” shall not be used for tattooing purposes. 9. This entry does not apply to substances that are gases at temperature of 20 °C and pressure of 101,3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50 °C, with the exception of formaldehyde (CAS No 50-00-0, EC No 200-001-8). 10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to a medical device, within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device or an accessory to a medical device, within the same meaning. Where the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device, the requirements of Regulation (EU) 2017/745 and of this Regulation shall apply cumulatively.

(*) Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).’;

(2) the following Appendix 13 is added:

‘Appendix 13

Entry 75- List of substances with specific concentration limits:

Substance name	EC No	CAS No	Concentration limit (by weight)
Mercury	231-106-7	7439-97-6	0,00005 %
Nickel	231-111-4	7440-02-0	0,0005 %
Organometallic tin	231-141-8	7440-31-5	0,00005 %
Antimony	231-146-5	7440-36-0	0,00005 %
Arsenic	231-148-6	7440-38-2	0,00005 %

Substance name	EC No	CAS No	Concentration limit (by weight)
Barium **	231-149-1	7440-39-3	0,05 %
Cadmium	231-152-8	7440-43-9	0,00005 %
Chromium‡	231-157-5	7440-47-3	0,00005 %
Cobalt	231-158-0	7440-48-4	0,00005 %
Copper **	231-159-6	7440-50-8	0,025 %
Zinc **	231-175-3	7440-66-6	0,2 %
Lead	231-100-4	7439-92-1	0,00007 %
Selenium	231-957-4	7782-49-2	0,0002 %
Benzo[a]pyrene	200-028-5	50-32-8, 63466-71-7	0,0000005 %
Polycyclic-aromatic Hydrocarbons (PAH), classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen or germ cell mutagen category 1A, 1B or 2			0,00005 % (individual concentrations)
Methanol	200-659-6	67-56-1	11 %
o-Anisidine **	201-963-1	90-04-0	0,0005 %
o-toluidine **	202-429-0	95-53-4	0,0005 %
3,3'-dichlorobenzidine **	202-109-0	91-94-1	0,0005 %
4-methyl-m- phenylenediamine **	202-453-1	95-80-7	0,0005 %
4-chloroaniline **	203-401-0	106-47-8	0,0005 %
5-nitro-o-toluidine **	202-765-8	99-55-8	0,0005 %
3,3'-dimethoxybenzidine **	204-355-4	119-90-4	0,0005 %
4,4'-bi-o-toluidine **	204-358-0	119-93-7	0,0005 %
4,4'-Thiodianiline **	205-370-9	139-65-1	0,0005 %
4-chloro-o-toluidine **	202-441-6	95-69-2	0,0005 %
2-naphthylamine **	202-080-4	91-59-8	0,0005 %
Aniline **	200-539-3	62-53-3	0,0005 %
Benzidine **	202-199-1	92-87-5	0,0005 %
p-toluidine **	203-403-1	106-49-0	0,0005 %
2-methyl-p-phenylenediamine **	202-442-1	95-70-5	0,0005 %
Biphenyl-4-ylamine **	202-177-1	92-67-1	0,0005 %
4-o-tolylazo-o-toluidine **	202-591-2	97-56-3	0,0005 %
4-methoxy-m- phenylenediamine **	210-406-1	615-05-4	0,0005 %
4,4'-methylenedianiline **	202-974-4	101-77-9	0,0005 %
4,4'-methylenedi-o-toluidine **	212-658-8	838-88-0	0,0005 %
6-methoxy-m-toluidine **	204-419-1	120-71-8	0,0005 %
4,4'- methylene-bis-[2-chloro aniline] **	202-918-9	101-14-4	0,0005 %

Substance name	EC No	CAS No	Concentration limit (by weight)
4,4'-oxydianiline **	202-977-0	101-80-4	0,0005 %
2,4,5-trimethylaniline **	205-282-0	137-17-7	0,0005 %
4-Aminoazobenzene **	200-453-6	60-09-3	0,0005 %
p-Phenylenediamine **	203-404-7	106-50-3	0,0005 %
Sulphanilic acid **	204-482-5	121-57-3	0,0005 %
4-amino-3-fluorophenol **	402-230-0	399-95-1	0,0005 %
2,6-xylidine	201-758-7	87-62-7	0,0005 %
6-amino-2-ethoxynaphthaline		293733-21-8	0,0005 %
2,4-xylidine	202-440-0	95-68-1	0,0005 %
Pigment Red 7 (PR7)/CI 12420	229-315-3	6471-51-8	0,1 %
Pigment Red 9(PR9)/CI 12460	229-104-6	6410-38-4	0,1 %
Pigment Red 15 (PR15)/CI 12465	229-105-1	6410-39-5	0,1 %
Pigment Red 210(PR210)/CI 12477	612-766-9	61932-63-6	0,1 %
Pigment Orange 74 (PO74)		85776-14-3	0,1 %
Pigment Yellow 65 (PY65)/CI 11740	229-419-9	6528-34-3	0,1 %
Pigment Yellow 74 (PY74)/CI 11741	228-768-4	6358-31-2	0,1 %
Pigment Red 12 (PR12)/CI 12385	229-102-5	6410-32-8	0,1 %
Pigment Red 14 (PR14)/CI 12380	229-314-8	6471-50-7	0,1 %
Pigment Red 17 (PR17)/CI 12390	229-681-4	6655-84-1	0,1 %
Pigment Red 112 (PR112)/CI 12370	229-440-3	6535-46-2	0,1 %
Pigment Yellow 14 (PY14)/CI 21095	226-789-3	5468-75-7	0,1 %
Pigment Yellow 55 (PY55)/CI 21096	226-789-3	6358-37-8	0,1 %
Pigment Red 2 (PR2)/CI 12310	227-930-1	6041-94-7	0,1 %
Pigment Red 22 (PR22)/CI 12315	229-245-3	6448-95-9	0,1 %
Pigment Red 146 (PR146)/CI 12485	226-103-2	5280-68-2	0,1 %
Pigment Red 269 (PR269)/CI 12466	268-028-8	67990-05-0	0,1 %
Pigment Orange16 (PO16)/CI 21160	229-388-1	6505-28-8	0,1 %
Pigment Yellow 1 (PY1)/CI 11680	219-730-8	2512-29-0	0,1 %
Pigment Yellow 12 (PY12)/CI 21090	228-787-8	6358-85-6	0,1 %
Pigment Yellow 87 (PY87)/CI 21107:1	239-160-3	15110-84-6, 14110-84-6	0,1 %
Pigment Yellow 97 (PY97)/CI 11767	235-427-3	12225-18-2	0,1 %
Pigment Orange 13 (PO13)/CI 21110	222-530-3	3520-72-7	0,1 %
Pigment Orange 34 (PO34)/CI 21115	239-898-6	15793-73-4	0,1 %
Pigment Yellow 83 (PY83)/CI 21108	226-939-8	5567-15-7	0,1 %
Solvent Red 1 (SR1)/CI 12150	214-968-9	1229-55-6	0,1 %

Substance name	EC No	CAS No	Concentration limit (by weight)
Acid Orange 24 (AO24)/CI 20170	215-296-9	1320-07-6	0,1 %
Solvent Red 23 (SR23)/CI 26100	201-638-4	85-86-9	0,1 %
Acid Red 73 (AR73)/CI 27290	226-502-1	5413-75-2	0,1 %
Disperse Yellow 3/CI 11855	220-600-8	2832-40-8	0,1 %
Acid Green 16	603-214-8	12768-78-4	0,1 %
Acid Red 26	223-178-3	3761-53-3	0,1 %
Acid Violet 17	223-942-6	4129-84-4	0,1 %
Basic Red 1	213-584-9	989-38-8	0,1 %
Disperse Blue 106	602-285-2	12223-01-7	0,1 %
Disperse Blue 124	612-788-9	61951-51-7	0,1 %
Disperse Blue 35	602-260-6	12222-75-2	0,1 %
Disperse Orange 37	602-312-8	12223-33-5	0,1 %
Disperse Red 1	220-704-3	2872-52-8	0,1 %
Disperse Red 17	221-665-5	3179-89-3	0,1 %
Disperse Yellow 9	228-919-4	6373-73-5	0,1 %
Pigment Violet 3	603-635-7	1325-82-2	0,1 %
Pigment Violet 39	264-654-0	64070-98-0	0,1 %
Solvent Yellow 2	200-455-7	60-11-7	0,1 %’

** Soluble. ‡Chromium VI.

COMMISSION IMPLEMENTING REGULATION (EU) 2020/2082

of 14 December 2020

on setting the weighted average of maximum mobile termination rates across the Union and repealing Implementing Regulation (EU) 2019/2116

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 531/2012 of the European Parliament and of the Council of 13 June 2012 on roaming on public mobile communications networks within the Union ([1]), and in particular Article 6e(2) thereof,

Whereas:

(1) Under Regulation (EU) No 531/2012, from 15 June 2017 domestic providers should not levy any surcharge in addition to the domestic retail price on roaming customers in any Member State for any regulated roaming call received, where those calls are within the limits allowed by the fair use policy.

(2) Regulation (EU) No 531/2012 limits any surcharge applied for receiving regulated roaming calls to the weighted average of maximum mobile termination rates across the Union.

(3) Commission Implementing Regulation (EU) 2019/2116 ([2]) sets out the weighted average of maximum mobile termination rates across the Union, to be applied in 2020 on the basis of the data values as of 1 July 2019.

(4) The Body of European Regulators for Electronic Communications has provided the Commission with updated information from Member States' national regulatory authorities on the maximum level of mobile termination rates imposed, under Articles 7 and 16 of Directive 2002/21/EC of the European Parliament and of the Council ([3]) and Article 13 of Directive 2002/19/EC of the European Parliament and of the Council ([4]) in each national market for wholesale voice call termination on individual mobile networks and on the total number of subscribers in the Member States.

(5) Under Regulation (EU) No 531/2012, the Commission has calculated the weighted average of the maximum mobile termination rates across the Union by multiplying the maximum mobile termination rate permitted in a given Member State by the total number of subscribers in that Member State, summing that product over all Member States and then dividing the total obtained by the total number of subscribers in all Member States, on the basis of the data values as of 1 July 2020. For Member States whose currency is not the euro, the relevant exchange rate is the average for the second quarter of 2020 obtained from the European Central Bank's database.

(6) It is therefore necessary to update the value of the weighted average of maximum mobile termination rates across the Union.

(7) Implementing Regulation (EU) 2019/2116 should therefore be repealed.

(8) Under Regulation (EU) No 531/2012, the Commission should annually review the weighted average of maximum mobile termination rates across the Union as set by this Implementing Regulation.

([1]) OJ L 172, 30.6.2012, p. 10.

([2]) Commission Implementing Regulation (EU) 2019/2116 of 28 November 2019 setting the weighted average of maximum mobile termination rates across the Union and repealing Implementing Regulation (EU) 2018/1979 (OJ L 320, 11.12.2019, p. 11).

([3]) Directive 2002/21/EC of the European Parliament and of the Council of 7 March 2002 on a common regulatory framework for electronic communications networks and services (Framework Directive) (OJ L 108, 24.4.2002, p. 33).

([4]) Directive 2002/19/EC of the European Parliament and of the Council of 7 March 2002 on access to, and interconnection of, electronic communications networks and associated facilities (Access Directive) (OJ L 108, 24.4.2002, p. 7.

(9) The measures provided for in this Regulation are in line with the opinion of the Communications Committee, established by Article 22 of Directive 2002/21/EC,

HAS ADOPTED THIS REGULATION:

Article 1

The weighted average of maximum mobile termination rates across the Union shall be EUR 0,0076 per minute.

Article 2

Implementing Regulation (EU) 2019/2116 is repealed.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2021.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 December 2020.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2020/2083

of 14 December 2020

amending Annex I to Regulation (EC) No 798/2008 as regards the entry for Japan in the list of third countries, territories, zones or compartments from which certain poultry commodities may be imported into or transit through the Union in relation to highly pathogenic avian influenza

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption ([1]), and in particular the introductory phrase of Article 8, the first subparagraph of point 1 of Article 8, point 4 of Article 8 and Article 9(4) thereof,

Having regard to Council Directive 2009/158/EC of 30 November 2009 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs ([2]), and in particular Articles 23(1) and 25(2) thereof,

Whereas:

(1) Commission Regulation (EC) No 798/2008 ([3]) lays down veterinary certification requirements for imports into and transit, including storage during transit, through the Union of poultry and poultry products (the commodities). It provides that the commodities are only to be imported into and transit through the Union from the third countries, territories, zones or compartments listed in columns 1 and 3 of the table in Part 1 of Annex I thereto.

(2) Regulation (EC) No 798/2008 also lays down the conditions for a third country, territory, zone or compartment to be considered as free from highly pathogenic avian influenza (HPAI).

(3) Japan is listed in the table in Part 1 of Annex I to Regulation (EC) No 798/2008 as a third country from which imports into and transit through the Union of certain poultry commodities are authorised from the whole of its territory.

(4) On 5 November 2020, Japan confirmed the presence of HPAI of subtype H5 in a poultry holding on its territory. Due to that confirmed outbreak of HPAI, Japan can no longer be considered as free from that disease and the veterinary authorities of Japan can therefore no longer certify consignments of meat of poultry for human consumption intended for import into or transit through the Union.

(5) The entry for Japan in the table in Part 1 of Annex I to Regulation (EC) No 798/2008 should therefore be amended to take account of the epidemiological situation in that third country.

(6) Annex I to Regulation (EC) No 798/2008 should therefore be amended accordingly.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([1]) OJ L 18, 23.1.2003, p. 11.
([2]) OJ L 343, 22.12.2009, p. 74.
([3]) Commission Regulation (EC) No 798/2008 of 8 August 2008 laying down a list of third countries, territories, zones or compartments from which poultry and poultry products may be imported into and transit through the Community and the veterinary certification requirements (OJ L 226, 23.8.2008, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

Part 1 of Annex I to Regulation (EC) No 798/2008 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 December 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Part 1 of Annex I to Regulation (EC) No 798/2008, the entry for Japan is replaced by the following:

ISO code and name of third country or territory	Code of third country, territory, zone or compart-ment	Description of third country, territory, zone or compartment	Veterinary certificate		Specific conditions	Specific conditions		Avian influenza surveillance status	Avian influenza vaccination status	Salmonella Control Status[6]
			Model(s)	Additional guarantees		Closing date[1]	Opening date[2]			
1	2	3	4	5	6	6A	6B	7	8	9
'JP – Japan	JP-0	Whole country	EP, E							
			POU		P2	5.11.2020'				

COMMISSION IMPLEMENTING REGULATION (EU) 2020/2084

of 14 December 2020

amending and correcting Implementing Regulation (EU) 2018/2067 on the verification of data and on the accreditation of verifiers pursuant to Directive 2003/87/EC of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2003/87/EC of the European Parliament and of the Council of 13 October 2003 establishing a system for greenhouse gas emission allowance trading within the Union and amending Council Directive 96/61/EC ([1]), and in particular Article 10a(2) and the third subparagraph of Article 15 thereof,

Whereas:

(1) To ensure consistency between verification of annual emissions reports pursuant to Article 15 of Directive 2003/87/EC and verification of activity level data collected pursuant to Commission Implementing Regulation (EU) 2019/1842 ([2]), as well as to make use of the synergies, it is appropriate to include rules for the verification of annual activity level reports required under Article 3 of Implementing Regulation (EU) 2019/1842 in the legal framework set by Commission Implementing Regulation (EU) 2018/2067 ([3]).

(2) Harmonised standards such as the harmonised standard concerning requirements for greenhouse gas validation and verification bodies for use in accreditation or other forms of recognition are regularly revised. A number of amendments should be made to Implementing Regulation (EU) 2018/2067 to align it with revisions in the applicable standards and to strengthen the requirements for procedures of verifiers and for the operation of the verifier's management system.

(3) It is important to clarify that the presumption of conformity laid down in Article 4 of Implementing Regulation (EU) 2018/2067 does not exempt the verifier from applying the programme specific requirements in that Implementing Regulation and that that presumption of conformity does not apply to certain provisions in Implementing Regulation (EU) 2018/2067 where it is important to preserve the objectives and principles set out in Annex V to Directive 2003/87/EC.

(4) Under Commission Delegated Regulation (EU) 2019/331 ([4]) and Implementing Regulation (EU) 2019/1842, the operator of an installation applying for free allocation in accordance with Article 10a of Directive 2003/87/EC is required to include the relevant monitoring provisions in a monitoring methodology plan. Therefore, it is no longer appropriate to provide for the verification of elements relevant for such free allocation in the scope of verification of the monitoring plan under Implementing Regulation (EU) 2018/2067.

(5) In order to ensure that the evaluation of verification may be carried out in efficient and timely manner, the rules regarding access of the competent authority to internal verification documentation should be amended.

([1]) OJ L 275, 25.10.2003, p. 32.

([2]) Commission Implementing Regulation (EU) 2019/1842 of 31 October 2019 laying down rules for the application of Directive 2003/87/EC of the European Parliament and of the Council as regards further arrangements for the adjustments to free allocation of emission allowances due to activity level changes (OJ L 282, 4.11.2019, p. 20).

([3]) Commission Implementing Regulation (EU) 2018/2067 of 19 December 2018 on the verification of data and on the accreditation of verifiers pursuant to Directive 2003/87/EC of the European Parliament and of the Council (OJ L 334, 31.12.2018, p. 94).

([4]) Commission Delegated Regulation (EU) 2019/331 of 19 December 2018 determining transitional Union-wide rules for harmonised free allocation of emission allowances pursuant to Article 10a of Directive 2003/87/EC of the European Parliament and of the Council (OJ L 59, 27.2.2019, p. 8).

(6) To further promote harmonisation within the Union and to improve the effectiveness of the accreditation system, it is important to clarify the eligibility of verifiers requesting accreditation in accordance with Implementing Regulation (EU) 2018/2067.

(7) Following the publication of Implementing Regulation (EU) 2018/2067, errors of different types have been detected and need to be corrected. In particular, throughout the text, the number of Delegated Regulation 2019/331 was omitted and needs to be inserted.

(8) Force majeure circumstances beyond the control of the operator or aircraft operator may prevent the verifier from carrying out physical site visits according to Article 21 of Implementing Regulation (EU) 2018/2067. In these cases it is appropriate to allow verifiers to carry out virtual site visits provided specific conditions are met.

(9) Implementing Regulation (EU) 2018/2067 should therefore be amended and corrected accordingly.

(10) It is appropriate for the amendments to Implementing Regulation (EU) 2018/2067 to apply to the verification of greenhouse gas emissions, tonne-kilometre data and allocation data related to the fourth trading period. The applicability of the relevant provisions of this Regulation should therefore be deferred to 1 January 2021.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Climate Change Committee,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Implementing Regulation (EU) 2018/2067

Implementing Regulation (EU) 2018/2067 is amended as follows:

(1) Article 2 is replaced by the following:

'*Article 2*

Scope

This Regulation shall apply to the verification of greenhouse gas emissions and tonne-kilometre data occurring from 1 January 2019, reported pursuant to Article 14 of Directive 2003/87/EC, and to the verification of data relevant for the update of *ex ante* benchmarks and for the determination of free allocation to installations pursuant to Article 10a of that Directive.';

(2) Article 3 is amended as follows:

(a) point (3) is replaced by the following:

'(3) "verifier" means a legal person carrying out verification activities pursuant to this Regulation and accredited by a national accreditation body pursuant to Regulation (EC) No 765/2008 and this Regulation or a natural person otherwise authorised, without prejudice to Article 5(2) of that Regulation, at the time a verification report is issued;';

(b) the following point (6a) is inserted:

'(6a) "annual activity level report" means a report submitted by an operator pursuant to Article 3(3) of Commission Implementing Regulation (EU) 2019/1842 (*);

(*) Commission Implementing Regulation (EU) 2019/1842 of 31 October 2019 laying down rules for the application of Directive 2003/87/EC of the European Parliament and of the Council as regards further arrangements for the adjustments to free allocation of emission allowances due to activity level changes (OJ, L 282, 4.11.2019, p. 20).';

(c) point (7) is replaced by the following:

'(7) "operator's or aircraft operator's report" means the annual emission report to be submitted by the operator or aircraft operator pursuant to Article 14(3) of Directive 2003/87/EC, the tonne-kilometre report to be submitted by the aircraft operator for the purposes of applying for the allocation of allowances pursuant to Articles 3e and 3f of that Directive, the baseline data report submitted by the operator pursuant to Article 4 (2) of Delegated Regulation (EU) 2019/331, the new entrant data report submitted by the operator pursuant to Article 5(2) of that Regulation or the annual activity level report;';

(d) in point (13), point (c) is replaced by the following:

'(c) for the purposes of verifying the baseline data report submitted by the operator pursuant to Article 4(2)(a) of Delegated Regulation (EU) 2019/331, the new entrant data report submitted by the operator pursuant to Article 5(2) of that Regulation or the annual activity level report, any act or omission of an act by the operator that is contrary to the requirements in the monitoring methodology plan;';

(e) the following point (30) is added:

'(30) "activity level reporting period" means the applicable period preceding the submission of the annual activity level report pursuant to Article 3(1) of Implementing Regulation (EU) 2019/1842.';

(3) Article 4 is replaced by the following:

'*Article 4*

Presumption of conformity

Where a verifier demonstrates its conformity with the criteria laid down in the relevant harmonised standards as defined in point (9) of Article 2 of Regulation (EC) No 765/2008, or parts thereof, the references of which have been published in the *Official Journal of the European Union*, it shall, with the exception of Articles 7(1), 7(4), 22, 27(1), 28, 31 and 32 of this Regulation, be presumed to comply with the requirements set out in Chapters II and III of this Regulation in so far as the applicable harmonised standards cover those requirements.';

(4) in Article 6, the first paragraph is replaced by the following:

'A verified emissions report, tonne-kilometre report, baseline data report, new entrant data report or annual activity level report shall be reliable for users. It shall represent faithfully that, which it either purports to represent or may reasonably be expected to represent.';

(5) Article 7 is amended as follows:

(a) paragraph 4 is amended as follows:

(i) point (a) is replaced by the following:

'(a) the operator's or aircraft operator's report is complete and meets the requirements laid down in Annex X to Implementing Regulation (EU) 2018/2066, in Annex IV to Delegated Regulation (EU) 2019/331 or Article 3(2) of Implementing Regulation (EU) 2019/1842, as appropriate;';

(ii) point (c) is replaced by the following:

'(c) where the verification of an operator's baseline data report, new entrant data report or annual activity level report is concerned, the operator has acted in conformance with the requirements of the monitoring methodology plan pursuant to Article 8 of Delegated Regulation (EU) 2019/331 approved by the competent authority;';

(b) paragraph 5 is replaced by the following:

'5. If the verifier discovers that an operator or an aircraft operator is not complying with Implementing Regulation (EU) 2018/2066 or the operator is not complying with, Delegated Regulation (EU) 2019/331 or Implementing Regulation (EU) 2019/1842, that irregularity shall be included in the verification report even if the monitoring plan or monitoring methodology plan concerned, as appropriate, has been approved by the competent authority.';

(6) Article 10(1) is amended as follows:

(a) point (h) is replaced by the following:

'(h) the operator's or aircraft operator's annual emission, tonne-kilometre report, baseline data report, new entrant data report or annual activity level report, as appropriate;';

(b) the following point (ka) is inserted:

'(ka) if the monitoring methodology plan was modified, a record of all modifications in accordance with Article 9 of Delegated Regulation (EU) 2019/331;';

(c) the following point (la) is inserted:

'(la) where applicable, information on how the operator has corrected non-conformities or addressed recommendations of improvements that were reported in the verification report concerning an annual activity level report from the previous year or a relevant baseline data report;';

(d) point (n) is replaced by the following:

'(n) all relevant correspondence with the competent authority, in particular information related to the notification of modifications of the monitoring plan or monitoring methodology plan as well as corrections of reported data, as appropriate;';

(7) Article 11(4) is amended as follows:

(a) point (b) is replaced by the following:

'(b) whether there have been any modifications to the monitoring plan during the reporting period;';

(b) the following point (ba) is inserted:

'(ba) whether there have been any modifications to the monitoring methodology plan during the baseline period or the activity level reporting period, as appropriate;';

(c) point (d) is replaced by the following:

'(d) where applicable, whether the modifications referred to in point (ba) have been notified to the competent authority pursuant to Article 9(3) of Delegated Regulation (EU) 2019/331 or approved by the competent authority in accordance with Article 9(4) of that Regulation.';

(8) in Article 13(1), point (c) is replaced by the following:

'(c) a data sampling plan setting out the scope and methods of data sampling related to data points underlying the aggregated emissions in the operator or aircraft operator's emission report, the aggregated tonne-kilometre data in the aircraft operator's tonne-kilometre report or the aggregated data relevant for free allocation in the operator's baseline data report, new entrant data report or annual activity level report.';

(9) Article 16(2) is amended as follows:

(a) point (b) is replaced by the following:

'(b) for the purposes of verifying an operator's baseline data report, new entrant data report or annual activity level report, the boundaries of an installation and its sub-installations;';

(b) point (c) is replaced by the following:

'(c) for the purposes of verifying an operator's emission report, baseline data report, new entrant data report or annual activity level report, the completeness of source streams and emission sources as described in the monitoring plan approved by the competent authority or monitoring methodology plan, as appropriate;';

(c) the following point (fa) is inserted:

'(fa) for the purposes of verifying an annual activity level report, the accuracy of the parameters listed in Articles 16(5), 19, 20, 21 or 22 of Delegated Regulation (EU) 2019/331 as well as data required under paragraphs 1, 2 and 4 of Article 6 of Implementing Regulation (EU) 2019/1842;';

(10) Article 17 is amended as follows:

(a) paragraph 3 is amended as follows:

(i) the introductory sentence is replaced by the following:

'For the purposes of verifying the operator's baseline data report, new entrant data report or annual activity level report, the verifier shall check whether the methodology for collecting and monitoring data defined in the monitoring methodology plan is applied in the correct way, including:';

(ii) the following points (e) to (h) are added:

'(e) whether the energy consumption has been correctly attributed to each sub-installation where applicable;

(f) whether the value of the parameters listed in Articles 16(5), 19, 20, 21 or 22 of Delegated Regulation (EU) 2019/331 is based on a correct application of that Regulation;

(g) for the purposes of verifying an annual activity level report and a new entrant data report, the date of start of normal operation as referred to in Article 5(2) of Delegated Regulation (EU) 2019/331;

(h) for the purposes of verifying an annual activity level report, whether the parameters listed in points 2.3 to 2.7 of Annex IV to Delegated Regulation (EU) 2019/331, as appropriate to the installation, have been monitored and reported in the correct way in accordance with the monitoring methodology plan.';

(b) paragraph 5 is deleted;

(11) in Article 18, paragraph 3 is replaced by the following:

'3. Where data gaps in baseline data reports, new entrant data reports or annual activity level reports have occurred, the verifier shall check whether methods are laid down in the monitoring methodology plan to deal with data gaps pursuant to Article 12 of Delegated Regulation (EU) 2019/331, whether those methods were appropriate for the specific situation and whether they have been applied correctly.

Where no applicable data gap method is laid down in the monitoring methodology plan, the verifier shall check whether the approach used by the operator to compensate for the missing data is based on reasonable evidence and ensures that the data required by Annex IV to Delegated Regulation (EU) 2019/331 or Article 3(2) of Implementing Regulation (EU) 2019/1842 are not underestimated or overestimated.';

(12) in Article 21, paragraphs 4 and 5 are replaced by the following:

'4. For the purposes of verifying the operator's baseline data report, new entrant data report and annual activity level report, the verifier shall also use a site visit to assess the boundaries of the installation and its sub-installations as well as the completeness of source streams, emission sources and technical connections.

5. For the purposes of verifying the operator's emission report, baseline data report, new entrant data report or annual activity level report the verifier shall decide, based on the risk analysis, whether visits to additional locations are needed, including where relevant parts of data flow activities and control activities are carried out in other locations such as company headquarters and other off-site offices.';

(13) Article 22 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) the first subparagraph is replaced by the following:

'If the verifier identifies misstatements, non-conformities or non-compliance with Implementing Regulation (EU) 2018/2066, Delegated Regulation (EU) 2019/331 or Implementing Regulation (EU) 2019/1842 as appropriate, during the verification, it shall inform the operator or aircraft operator thereof on a timely basis and request relevant corrections.';

(ii) the third subparagraph is replaced by the following:

'Where a non-compliance with Implementing Regulation (EU) 2018/2066, Delegated Regulation (EU) 2019/331 or Implementing Regulation (EU) 2019/1842 has been identified, the operator or aircraft operator shall notify the competent authority and correct the non-compliance as appropriate without undue delay.';

(b) paragraph 2 is replaced by the following:

'2. The verifier shall document and mark as resolved in the internal verification documentation all misstatements, non-conformities or non-compliance with Implementing Regulation (EU) 2018/2066, Delegated Regulation (EU) 2019/331 or Implementing Regulation (EU) 2019/1842 that have been corrected by the operator or aircraft operator during the verification.';

(c) in paragraph 3, the fourth subparagraph is replaced by the following:

'If the operator or aircraft operator does not correct the non-compliance with Implementing Regulation (EU) 2018/2066, Delegated Regulation (EU) 2019/331 or Implementing Regulation (EU) 2019/1842 in accordance with paragraph 1 before the verifier issues the verification report, the verifier shall assess whether the uncorrected non-compliance has an impact on the reported data and whether this leads to material misstatement.'.

(14) in Article 23(4), the introductory sentence is replaced by the following:

'For the purposes of verifying baseline data report, new entrant data reports or annual activity level reports, the materiality level shall be 5 % of the total reported value of the following:';

(15) in Article 26, paragraph 3 is replaced by the following:

'3. The verifier shall, upon request, provide the competent authority access to the internal verification documentation and other relevant information to facilitate an evaluation of the verification by the competent authority. The competent authority can set a timeframe within which the verifier must provide access to that documentation.';

(16) Article 27 is amended as follows:

(a) in paragraph 1, the introductory sentence is replaced by the following:

'Based on the information collected during the verification, the verifier shall issue a verification report to the operator or aircraft operator on each emission report, tonne-kilometre report, baseline data report, new entrant data report or annual activity level report that was subject to verification.';

(b) paragraph 3 is amended as follows:

(i) the following point (ha) is inserted:

'(ha) where it concerns the verification of the annual activity level report, aggregated annual verified data for each year in the activity level reporting period for each sub-installation for its annual activity level;';

(ii) point (i) is replaced by the following:

'(i) the reporting period, the baseline period or the activity level reporting period subject to verification;';

(iii) point (o) is replaced by the following:

'(o) any issues of non-compliance with Implementing Regulation (EU) 2018/2066, Delegated Regulation (EU) 2019/331 or Implementing Regulation (EU) 2019/1842 which have become apparent during the verification;';

(iv) point (r) is deleted;

(v) the following points are inserted:

'(ra) where the verifier has observed relevant changes to the parameters listed in Articles 16(5), 19, 20, 21 or 22 of Delegated Regulation (EU) 2019/331 or changes in the energy efficiency pursuant to paragraphs 1, 2 and 3 of Article 6 of Implementing Regulation 2019/1842, a description of those changes and related remarks;

(rb) where applicable, confirmation that the date of start of normal operation as referred to in Article 5(2) of Delegated Regulation (EU) 2019/331 has been checked;';

(c) paragraph 4 is amended as follows:

(i) the introductory sentence is replaced by the following:

'The verifier shall describe the misstatements, non-conformities and non-compliance with Implementing Regulation (EU) 2018/2066, Delegated Regulation (EU) 2019/331 or Implementing Regulation (EU) 2019/1842 in sufficient detail in the verification report to allow the operator or aircraft operator as well as the competent authority to understand the following:';

(ii) point (a) is replaced by the following:

'(a) the size and nature of the misstatement, non-conformity or non-compliance with Implementing Regulation (EU) 2018/2066, Delegated Regulation (EU) 2019/331 or Implementing Regulation (EU) 2019/1842;';

(iii) point (d) is replaced by the following:

'(d) to which Article in Implementing Regulation (EU) 2018/2066, Delegated Regulation (EU) 2019/331 or Implementing Regulation (EU) 2019/1842 the non-compliance relates.';

(17) in Article 29, the following paragraph 1a is inserted:

'1a. For the purposes of the verification of the annual activity level report, the verifier shall assess whether the operator has corrected the non-conformities indicated in the verification report related to the corresponding baseline data report, the new entrant data report or the annual activity level report from the previous activity level reporting period.

If the operator has not corrected those non-conformities, the verifier shall consider whether the omission increases or may increase the risk of misstatements.

The verifier shall report in the verification report whether those non-conformities have been resolved by the operator.';

(18) in Article 30(1), point (e) is replaced by the following:

'(e) the monitoring and reporting of data for baseline data reports, new entrant data reports and annual activity level reports.';

(19) Article 31 is amended as follows:

(a) paragraph 3 is amended as follows:

(i) points (a) and (b) are replaced by the following:

'(a) when an operator's emission report or annual activity level report is verified for the first time by the verifier;

(b) for the purposes of verifying the operator's emission report, if a verifier has not carried out a site visit in two reporting periods immediately preceding the current reporting period;';

(ii) the following point (ba) is inserted:

'(ba) for the purposes of verifying the operator's annual activity level report, if a verifier has not carried out a site visit during the verification of an annual activity level report or a baseline data report in the two activity level reporting periods immediately preceding the current activity level reporting period;';

(iii) the following point (ca) is inserted:

'(ca) if, during the activity level reporting period, there have been significant changes to the installation or its sub-installations which require significant modifications to the monitoring methodology plan, including those changes referred to in Article 9(5) of Delegated Regulation (EU) 2019/331;';

(b) paragraph 4 is replaced by the following:

'4. Points (c) and (ca) of paragraph 3 are not applicable where, during the reporting period, there have been only modifications of the default value as referred to in Article 15(3)(h) of Implementing Regulation (EU) 2018/2066 or Article 9(5)(c) of Delegated Regulation (EU) 2019/331.';

(20) Article 32 is amended as follows:

(a) in point (1), the introductory sentence is replaced by the following:

'the verification of an operator's emission report concerns a category A installation referred to in Article 19(2)(a) of Implementing Regulation (EU) 2018/2066 or a category B installation referred to in Article 19(2)(b) of that Implementing Regulation whereby:';

(b) in point (2), the introductory sentence is replaced by the following:

'the verification of an operator's emission report concerns a category A installation referred to in Article 19(2)(a) of Implementing Regulation (EU) 2018/2066 or a category B installation referred to in Article 19(2)(b) of that Implementing Regulation whereby:';

(c) point (3) is replaced by the following:

'(3) the verification of an operator's emission report concerns an installation with low emissions as referred to in Article 47(2) of Implementing Regulation (EU) 2018/2066 and paragraphs (a) to (c) of point (2) are applicable.';

(d) the following points (3a), (3b) and (3c) are inserted:

'(3a) the verification of an operator's annual activity level report concerns an installation as referred to in point 1, 2 or 3 whereby:

(a) that installation has no other sub-installation than one sub-installation to which a product benchmark pursuant to Article 10(2) of Delegated Regulation (EU) 2019/331 is applicable; and

(b) the production data relevant for the product benchmark has been evaluated as part of an audit for financial accounting purposes and the operator provides evidence thereof.

(3b) the verification of an operator's annual activity level report concerns an installation as referred to in point 1, 2 or 3 whereby:

(a) the installation has a maximum of two sub-installations;

(b) the second sub-installation contributes less than 5 % to the installation's total final allocation of allowances; and

(c) the verifier has sufficient data available to assess the split of sub-installations if relevant;

(3c) the verification of an operator's annual activity level report concerns an installation as referred to in point 1, 2 or 3 whereby:

(a) the installation has only heat benchmark or district heating sub-installations; and

(b) the verifier has sufficient data available to assess the split of sub-installations if relevant;';

(e) point (4) is amended as follows:

(a) the introductory sentence is replaced by the following:

'the verification of the operator's emission report or annual activity level report concerns an installation located on an unmanned site whereby:';

(b) point (c) is replaced by the following:

'(c) the meters have already been inspected on site by the operator or a laboratory in accordance with Article 60 of Implementing Regulation (EU) 2018/2066 or Article 11 of Delegated Regulation (EU) 2019/331 and a signed document or date-stamped photographic evidence provided by the operator demonstrates that no metering or operational changes have occurred at the installation since that inspection;';

(f) point (5) is amended as follows:

(a) the first paragraph is amended as follows:

(i) the introductory sentence is replaced by the following:

'the verification of the operator's emission report or annual activity level report concerns an installation located on a remote or inaccessible site, in particular an off-shore installation, whereby:';

(ii) point (b) is replaced by the following:

'(b) the meters have already been inspected on site by the operator or a laboratory in accordance with Article 60 of Implementing Regulation (EU) 2018/2066 or Article 11 of Delegated Regulation (EU) 2019/331 and a signed document or date-stamped photographic evidence provided by the operator demonstrates that no metering or operational changes have occurred at the installation since that inspection.';

(b) the following paragraph is added:

'Point (3a)(b) must be applied if the sub-installation contributing 95 % or more to the installation's total final allocation of allowances as referred to in point (3b)(b) is a sub-installation to which a product benchmark pursuant to Article 10(2) of Delegated Regulation (EU) 2019/331 is applicable.';

(21) the following Article is inserted:

'*Article 34a*

Virtual site visits

1. By way of derogation from Article 21(1), where serious, extraordinary and unforeseeable circumstances, outside the control of the operator or aircraft operator, prevent the verifier from carrying out a physical site visit and where these circumstances cannot, after using all reasonable efforts, be overcome, the verifier may decide, subject to the approval of the competent authority in accordance with paragraph 3 of this Article, to carry out a virtual site visit.

The verifier shall take measures to reduce the verification risk to an acceptable level to obtain reasonable assurance that the operator's or aircraft operator's report is free from material misstatements. A physical visit to the site of the installation or aircraft operator shall be carried out without undue delay.

The decision to carry out a virtual site visit shall be based on the outcome of the risk analysis and after determining that the conditions for carrying out a virtual site visit are met. The verifier shall inform the operator or aircraft operator thereof without undue delay.

2. The operator or aircraft operator shall submit an application to the competent authority requesting the competent authority to approve the verifier's decision to carry out a virtual site visit. The application shall include the following elements:

(a) evidence that it is not possible to carry out a physical site visit because of the serious, extraordinary and unforeseeable circumstances, outside the control of the operator or aircraft operator;

(b) information on how the virtual site visit will be carried out;

(c) the information on the outcome of the risk analysis by the verifier;

(d) evidence of the measures taken by the verifier to reduce the verification risk to an acceptable level to obtain reasonable assurance that the operator's or aircraft operator's report is free from material misstatements.

3. On an application submitted by the operator or aircraft operator concerned, the competent authority shall decide whether to approve the verifier's decision to carry out a virtual site visit, taking into consideration the elements specified in paragraph 2.

4. By way of derogation from paragraph 3, where a large number of installations or aircraft operators are affected by the similar serious, extraordinary and unforeseeable circumstances, outside the control of the operator or aircraft operator, and immediate action is needed because of legally imposed national health reasons, the competent authority may authorise verifiers to carry out virtual site visits without a need for an individual approval referred to in paragraph 3 provided that:

(a) the competent authority has established that there are serious extraordinary and unforeseeable circumstances, outside the control of the operator or aircraft operator and immediate action is needed because of legally imposed national health reasons;

(b) the operator or aircraft operator informs the competent authority about the verifier's decision to carry out a virtual site visit, including the elements specified in paragraph 2.

The competent authority shall review the information provided by the operator or aircraft operator in accordance with point (b) during the assessment of the operator's or aircraft operator's report and inform the national accreditation body about the outcome of the assessment.';

(22) in Article 37(5), the second subparagraph is replaced by the following:

'Where the verifier is carrying out verification of baseline data reports, new entrant data reports or annual activity level reports the verification team shall include in addition at least one person with the technical competence and understanding required to assess the specific technical aspects regarding the collection, monitoring and reporting of data relevant for free allocation.';

(23) in Article 38(1), point (a) is replaced by the following:

'(a) knowledge of Directive 2003/87/EC, Implementing Regulation (EU) 2018/2066, Delegated Regulation (EU) 2019/331 and Implementing Regulation (EU) 2019/1842 in the case of verification of the baseline data report, new entrant data report or annual activity level report, this Regulation, relevant standards, and other relevant legislation, applicable guidelines, as well as relevant guidelines and legislation issued by the Member State in which the verifier is carrying out a verification;';

(24) Article 41 is amended as follows:

(a) in paragraph 1, the second sentence is replaced by the following:

'When establishing and implementing these procedures and processes the verifier shall carry out the activities listed in Annex II of this Regulation in accordance with the harmonised standard referred to in that Annex.';

(b) paragraph 2 is replaced by the following

'2. A verifier shall design, document, implement and maintain a management system in accordance with the harmonised standard referred to in Annex II to ensure consistent development, implementation, improvement and review of the procedures and processes referred to in paragraph 1. The management system shall include at least the following:

(a) policies and responsibilities;

(b) management review;

(c) internal audits;

(d) corrective action;

(e) actions to address risk and opportunities and to take preventive action;

(f) control of documented information.';

(25) in Article 42, paragraph 1 is replaced by the following:

'1. A verifier shall maintain and manage records, including records on the competence and impartiality of personnel, to demonstrate compliance with this Regulation.';

(26) Article 43 is amended as follows:

(a) in paragraph 2, the second sentence is replaced by the following:

'For the purposes of this Regulation, the relevant requirements on the structure and organisation of the verifier laid down in the harmonised standard referred to in Annex II shall apply.';

(b) in the first subparagraph of paragraph 3, the following sentence is added:

'For this purpose, the verifier shall monitor the risks to impartiality and take appropriate action to address those risks.';

(c) paragraph 5 is amended as follows:

(a) in the first subparagraph, the first sentence is replaced by the following:

'A verifier shall not outsource the closing of the agreement between the operator or aircraft operator and the verifier, the independent review or the issuance of the verification report.';

(b) the second subparagraph is replaced by the following:

'However, contracting individuals to carry out verification activities shall not constitute outsourcing for the purposes of the first subparagraph if the verifier, when contracting those persons, takes full responsibility for the verification activities performed by contracted personnel. When contracting individuals for carrying out verification activities the verifier shall require these individuals to sign a written agreement that they comply with the procedures of the verifier and that there is no conflict of interest in carrying out these verification activities.';

(d) the following paragraph 6a is inserted:

'6a. When verifying the same operator or aircraft operator as in the previous year, the verifier shall consider the risk to impartiality and take measures to reduce the risk to impartiality.';

(e) the following paragraph 8 is added:

'8. If the EU ETS lead auditor undertakes annual verifications for a period of five consecutive years for a given installation, then the EU ETS lead auditor shall take a three consecutive year break from providing verification services to that same installation. The five years maximum period includes EU ETS verifications of emissions or allocation data performed for the installation starting after 1 January 2021.';

(27) in Article 44, the second subparagraph is replaced by the following:

'For the purpose of verifying baseline data reports, new entrant data reports or annual activity level reports, a verifier issuing a verification report to an operator shall in addition be accredited for activity group No 98 referred to in Annex I.';

(28) in Article 46(1), the first subparagraph is replaced by the following:

'Any legal person established under national law of a Member State may request accreditation pursuant to Article 5(1) of Regulation (EC) No 765/2008 and the provisions of this Chapter.';

(29) in Article 59(1), point (b) is replaced by the following:

'b) have knowledge of Directive 2003/87/EC, Implementing Regulation (EU) 2018/2066, Delegated Regulation (EU) 2019/331 and Implementing Regulation 2019/1842 where the assessor assesses the verifier's competence and performance for scope no 98 referred to in Annex I of this Regulation, this Regulation, relevant standards and other relevant legislation as well as applicable guidelines';

(30) in Article 60(2), point (a) is replaced by the following:

'(a) have knowledge of Directive 2003/87/EC, Implementing Regulation (EU) 2018/2066, Delegated Regulation (EU) 2019/331 and Implementing Regulation 2019/1842 where the technical expert assesses the verifier's competence and performance for scope no 98 referred to in Annex I of this Regulation, this Regulation, relevant standards, and other relevant legislation as well as applicable guidelines';

(31) in Article 77(1), point (b) is replaced by the following:

'(b) the address and contact details of the operators or aircraft operators whose emissions, tonne-kilometre reports, baseline data reports, new entrant data reports or annual activity level reports are subject to its verification;';

(32) Annex II is amended in accordance with the Annex to this Regulation.

Article 2

Corrections to Implementing Regulation (EU) 2018/2067

Implementing Regulation (EU) 2018/2067 is corrected as follows:

(1) Article 3 is corrected as follows:

(a) in point 11, '…/…' is replaced by '2019/331';

(b) in point 28, '…/…' is replaced by '2019/331';

(c) in point 29, '…/…' is replaced by '2019/331';

(2) the second subparagraph of Article 7(4) is amended as follows:

(a) in the first sentence, '…/…' is replaced by '2019/331';

(b) in the second sentence, '…/…' is replaced by '2019/331';

(3) in the second subparagraph of Article 7(6), '…/…' is replaced by '2019/331';

(4) Article 10(1) is corrected as follows:

(a) in point (e), '…/…' is replaced by '2019/331';

(b) in point (f), '…/…' is replaced by '2019/331';

(c) point (l) is replaced by the following:

'(l) where applicable, the reports referred to in Article 69(1) and 69(4) of Implementing Regulation (EU) 2018/2066;';

(5) Article 17(3) is corrected as follows:

(a) in point (a), '…/…' is replaced by '2019/331';

(b) in point (c), '…/…' is replaced by '2019/331';

(6) in Article 17(4), the first subparagraph is replaced by the following:

'4. Where transferred CO_2 is subtracted in accordance with Article 49 of Implementing Regulation (EU) 2018/2066 or transferred N_2O is not counted as emitted in accordance with Article 50 of that Regulation, and the CO_2 or N_2O transferred is measured by both the transferring and receiving installation, the verifier shall check whether differences between the measured values at both installations can be explained by the uncertainty of the measurement systems and whether the correct arithmetic average of the measured values has been used in the emission reports of both installations.';

(7) in Article 19(3), '…/…' is replaced by '2019/331';

(8) in point (e) of Article 27(1), '…/…' is replaced by '2019/331';

(9) Article 27(3) is corrected as follows:

(a) in point (f), '…/…' is replaced by '2019/331';

(b) in point (q), '…/…' is replaced by '2019/331';

(10) in point (e) of Article 28, '…/…' is replaced by '2019/331';

(11) in point (c) of Article 30(1), '…/…' is replaced by '2019/331';

(12) in the third subparagraph of Article 58(2), '…/…' is replaced by '2019/331';

(13) in Article 69(1), '…/…' is replaced by '2019/331'.

Article 3

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2021.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 December 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Annex II, the following points (g) and (h) are added:

'(g) a procedure or process to ensure that the verifier takes full responsibility for verification activities performed by contracted individuals;

(h) processes ensuring the proper functioning of the management system as referred to in Article 41(2), including:

i. processes for the review of management system at least once a year, not exceeding 15 months between management reviews;

ii. processes for conducting internal audits at least once a year, not exceeding 15 months between internal audits;

iii. processes for identifying and managing non-conformities in the verifier's activities and taking corrective action to address those non-conformities;

iv. processes for identifying risks and opportunities in verifier's activities and taking preventive actions to mitigate those risks;

v. processes for the control of documented information.'.

COMMISSION IMPLEMENTING REGULATION (EU) 2020/2085

of 14 December 2020

amending and correcting Implementing Regulation (EU) 2018/2066 on the monitoring and reporting of greenhouse gas emissions pursuant to Directive 2003/87/EC of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2003/87/EC of the European Parliament and of the Council of 13 October 2003 establishing a system for greenhouse gas emission allowance trading within the Union and amending Council Directive 96/61/EC ([1]), and in particular Article 14(1) thereof,

Whereas:

(1) Commission Implementing Regulation (EU) 2018/2066 ([2]) lays down rules for the monitoring and reporting of greenhouse gas emissions from the activities subject to Directive 2003/87/EC. In particular, Implementing Regulation (EU) 2018/2066 lays down rules on the monitoring of emissions from biomass which are consistent with the rules on the use of biomass laid down in Directive 2009/28/EC of the European Parliament and of the Council ([3]). Directive (EU) 2018/2001 of the European Parliament and of the Council ([4]) repeals Directive 2009/28/EC with effect from 1 July 2021. It is therefore appropriate to align the provisions regarding the monitoring and reporting of emissions from biomass laid down in Implementing Regulation (EU) 2018/2066 with the rules laid down in Directive (EU) 2018/2001, in particular as regards the relevant definitions and the sustainability and greenhouse gas emission saving criteria for the use of biomass. Furthermore, since Directive (EU) 2018/2001 lays down the sustainability and greenhouse gas emissions saving criteria for fuels when used for energy purposes, the sustainability criteria for biomass under Implementing Regulation (EU) 2018/2066 should apply only in the case of combustion of biomass in an installation or as a biofuel for aviation. For reasons of legal certainty, it is also necessary to clarify that where the biomass used for combustion does not comply with the sustainability and greenhouse gas emission saving criteria, its carbon content should be considered as fossil carbon.

(2) Pursuant to Commission Delegated Regulation (EU) 2019/331 ([5]) and Commission Implementing Regulation (EU) 2019/1842 ([6]), the operator of an installation applying for free allocation of allowances in accordance with Article 10a of Directive 2003/87/EC is required to include the relevant monitoring provisions in a monitoring methodology plan, subject to approval of the competent authority. No further elements need to be included in the monitoring plans of installations to which free allocation is given. Accordingly, it is no longer necessary to provide the Member States with the possibility to require the inclusion of such elements.

(3) During the transition phase between the notification of a modification of a monitoring plan and the approval of the new modified monitoring plan by the competent authority, any gap in the monitoring or any application of a less accurate methodology should be avoided. It should therefore be clarified that data collection in this transition period should be based on both the original and the modified monitoring plan and that records should be kept of both monitoring results.

([1]) OJ L 275, 25.10.2003, p. 32.

([2]) Commission Implementing Regulation (EU) 2018/2066 of 19 December 2018 on the monitoring and reporting of greenhouse gas emissions pursuant to Directive 2003/87/EC of the European Parliament and of the Council and amending Commission Regulation (EU) No 601/2012 (OJ L 334, 31.12.2018, p. 1).

([3]) Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC (OJ L 140, 5.6.2009, p. 16).

([4]) Directive (EU) 2018/2001 of the European Parliament and of the Council of 11 December 2018 on the promotion of the use of energy from renewable sources (OJ L 328, 21.12.2018, p. 82).

([5]) Commission Delegated Regulation (EU) 2019/331 of 19 December 2018 determining transitional Union-wide rules for harmonised free allocation of emission allowances pursuant to Article 10a of Directive 2003/87/EC of the European Parliament and of the Council (OJ L 59, 27.2.2019, p. 8).

([6]) Commission Implementing Regulation (EU) 2019/1842 of 31 October 2019 laying down rules for the application of Directive 2003/87/EC of the European Parliament and of the Council as regards further arrangements for the adjustments to free allocation of emission allowances due to activity level changes (OJ L 282, 4.11.2019, p. 20).

(4) With a view of ensuring accurate monitoring of source streams involving biogas injected into a gas grid, the rules on determination of the activity data from biogas should be improved and strengthened. In particular, the determination of the biomass fraction should depend on the actual purchase of biogas by the operator, and any potential double counting of the same biogas by different users should be avoided. On the basis of experience gained in application of the methodology for determining the biomass fraction of natural gas from a gas grid, the Commission will assess the need for a review of that methodology.

(5) Due to typical administrative and practical procedures at aerodromes, it is difficult to ascertain to which aircraft a batch of fuel is physically uplifted. Since aviation fuels are uniform in technical specifications, it is therefore appropriate to allow a monitoring approach for biofuel uplifts based on purchase data, provided that the relevant requirements laid down in Articles 29, 30 and 31 of Directive (EU) 2018/2001 are complied with.

(6) For consistency reasons, the rounding of data on emissions of greenhouse gases should be aligned with the way verified emissions are rounded in the Union Registry established in accordance with Article 19 of Directive 2003/87/EC.

(7) In order to reduce administrative burden for operators using certain mixed process materials, the distinction between inorganic carbon, mostly in form of carbonates, and organic carbon should be avoided where possible. In order to align common laboratory practice with the terminology of different source stream types, it is appropriate to include all forms of carbon in the same approach for process emissions. Therefore, the analysis of total carbon of a material instead of separate treatment of total inorganic carbon and total organic carbon should be allowed where possible. As a consequence, the expression 'non-carbonate carbon' should be used instead of 'organic carbon' to refer to all forms of carbon except carbonates.

(8) The fifth Assessment Report of the Intergovernmental Panel for Climate Change ([7]) provides new values for global warming potentials of greenhouse gases. The global warming potentials of greenhouse gases used in the EU Emission Trading System should therefore be adapted to those values and aligned with other Union acts.

(9) Following the publication of Implementing Regulation (EU) 2018/2066, an error has been detected in a formula used to determine the emissions of C_2F_6. That error should be corrected.

(10) Member States are to transpose Directive (EU) 2018/2001 by 30 June 2021. As the monitoring and reporting under Implementing Regulation (EU) 2018/2066 takes place on a calendar year basis, the amendments made in order to align the provisions of that Regulation to Directive (EU) 2018/2001 should start to apply only as of the beginning of the subsequent reporting period, that is from 1 January 2022. The date of application for the other amendments and the correction should be the same as for Implementing Regulation (EU) 2018/2066, that is 1 January 2021. Accordingly, the existing provisions of Implementing Regulation (EU) 2018/2066 on the monitoring and reporting on CO_2 emissions from biomass in accordance with Directive 2009/28/EC should continue to apply for the emissions occurring in 2021.

(11) Implementing Regulation (EU) 2018/2066 should therefore be amended and corrected accordingly.

(12) The measures provided for in this Regulation are in accordance with the opinion of the Climate Change Committee,

([7]) Column 'GWP 100-year' in Table 8.A.1 of Appendix 8.A of the report 'Climate Change 2013: The Physical Science Basis. Contribution of Working Group I to the Fifth Assessment Report of the Intergovernmental Panel on Climate Change', p. 731; available at https://www.ipcc.ch/assessment-report/ar5/

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Implementing Regulation (EU) 2018/2066

Implementing Regulation (EU) 2018/2066 is amended as follows:

(1) Article 3 is amended as follows:

(a) point (21) is replaced by the following:

'(21) "biomass" means the biodegradable fraction of products, waste and residues from biological origin from agriculture, including vegetal and animal substances, from forestry and related industries, including fisheries and aquaculture, as well as the biodegradable fraction of waste, including industrial and municipal waste of biological origin;';

(b) the following points (21a) to (21e) are inserted:

'(21a) "biomass fuels" means gaseous and solid fuels produced from biomass;

(21b) "biogas" means gaseous fuels produced from biomass;

(21c) "waste" means waste as defined in point (1) of Article 3 of Directive 2008/98/EC, excluding substances that have been intentionally modified or contaminated in order to meet this definition;

(21d) "residue" means a substance that is not the end product(s) that a production process directly seeks to produce; it is not a primary aim of the production process and the process has not been deliberately modified to produce it;

(21e) "agricultural, aquaculture, fisheries and forestry residues" means residues that are directly generated by agriculture, aquaculture, fisheries and forestry and that do not include residues from related industries or processing;';

(c) point (23) is replaced by the following:

'(23) "biofuels" means liquid fuels for transport produced from biomass;';

(2) in Article 12, paragraph 3 is deleted;

(3) in Article 16(1), the second subparagraph is replaced by the following:

'In case of doubt, the operator or aircraft operator shall use in parallel both the modified and the original monitoring plan to carry out all monitoring and reporting in accordance with both plans, and it shall keep records of both monitoring results.';

(4) in Article 18(2), the following third subparagraph is added:

'For the purpose of this paragraph, Article 38(5) shall apply, provided that the relevant information on the sustainability and the greenhouse gas emissions saving criteria of biofuels, bioliquids and biomass fuels used for combustion is available to the operator.';

(5) in Article 19, the following paragraph 6 is added:

'6. For the purpose of this Article, Article 38(5) shall apply.';

(6) Article 38 is amended as follows:

(a) in paragraph 1, the following subparagraph is added:

'For the purpose of this paragraph, Article 38(5) shall apply.';

(b) in paragraph 2, the first subparagraph is replaced with the following:

'The emission factor of biomass shall be zero. For the purpose of this subparagraph, Article 38(5) shall apply.';

(c) in paragraph 4, the following subparagraph is added:

'For the purpose of this paragraph, Article 38(5) shall apply.';

(d) the following paragraph 5 is added:

'5. Where reference is made to this paragraph, biofuels, bioliquids and biomass fuels used for combustion shall fulfil the sustainability and the greenhouse gas emissions saving criteria laid down in paragraphs 2 to 7 and 10 of Article 29 of Directive (EU) 2018/2001.

However, biofuels, bioliquids and biomass fuels produced from waste and residues, other than agricultural, aquaculture, fisheries and forestry residues are required to fulfil only the criteria laid down in Article 29(10) of Directive (EU) 2018/2001. This subparagraph shall also apply to waste and residues that are first processed into a product before being further processed into biofuels, bioliquids and biomass fuels.

Electricity, heating and cooling produced from municipal solid waste shall not be subject to the criteria laid down in Article 29(10) of Directive (EU) 2018/2001.

The criteria laid down in paragraphs 2 to 7 and 10 of Article 29 of Directive (EU) 2018/2001 shall apply irrespective of the geographical origin of the biomass.

Article 29(10) of Directive (EU) 2018/2001 shall apply to an installation as defined in Article 3(e) of Directive 2003/87/EC.

The compliance with the criteria laid down in paragraphs 2 to 7 and 10 of Article 29 of Directive (EU) 2018/2001 shall be assessed in accordance with Articles 30 and 31(1) of that Directive.

Where the biomass used for combustion does not comply with this paragraph, its carbon content shall be considered as fossil carbon.';

(7) Article 39 is amended as follows:

(a) paragraph 3 is replaced by the following:

'3. By way of derogation from paragraphs 1 and 2 and Article 30, the operator shall not use analyses or estimation methods in accordance with paragraph 2 to determine the biomass fraction of natural gas received from a gas grid to which biogas is added.

The operator may determine that a certain quantity of natural gas from the gas grid is biogas by using the methodology set out in paragraph 4.';

(b) the following paragraph 4 is added:

'4. The operator may determine the biomass fraction using purchase records of biogas of equivalent energy content, provided that the operator provides evidence to the satisfaction of the competent authority that:

(a) there is no double counting of the same biogas quantity, in particular that the biogas purchased is not claimed to be used by anyone else, including through a disclosure of a guarantee of origin as defined in Article 2(12) of Directive (EU) 2018/2001;

(b) the operator and the producer of the biogas are connected to the same gas grid.

For the purpose of demonstrating compliance with this paragraph, the operator may use the data recorded in a database set up by one or more Member States which enables tracing of transfers of biogas.';

(8) in Article 43(4), the following subparagraph is added:

'For the purpose of this paragraph, Article 38(5) shall apply.';

(9) in Article 47(2), the following subparagraph is added:

'For the purpose of this paragraph, Article 38(5) shall apply.';

(10) Article 54 is replaced by the following:

'Article 54

Specific provisions for biofuels

1. For mixed fuels, the aircraft operator may either assume the absence of biofuel and apply a default fossil fraction of 100 %, or determine a biofuel fraction in accordance with paragraphs 2 or 3.

2. Where biofuels are physically mixed with fossil fuels and delivered to the aircraft in physically identifiable batches, the aircraft operator may carry out analyses in accordance with Articles 32 to 35 to determine the biomass fraction, on the basis of a relevant standard and the analytical methods set out in those Articles, provided that the use of that standard and those analytical methods is approved by the competent authority. Where the aircraft operator provides evidence to the competent authority that such analyses would incur unreasonable costs or are technically not feasible, the aircraft operator may base the estimation of the biofuel content on a mass balance of fossil fuels and biofuels purchased.

3. Where purchased biofuel batches are not physically delivered to a specific aircraft, the aircraft operator shall not use analyses to determine the biomass fraction of the fuels used.

The aircraft operator may determine the biomass fraction using purchase records of biofuel of equivalent energy content, provided that the aircraft operator provides evidence to the satisfaction of the competent authority that there is no double counting of the same biofuel quantity, in particular that the biofuel purchased is not claimed to be used by anyone else.

For the purpose of demonstrating compliance with the requirements referred to in the second subparagraph, the operator may use the data recorded in the Union database set up in accordance with Article 28(2) of Directive (EU) 2018/2001.

4. The emission factor of biofuel shall be zero.

For the purpose of this paragraph, Article 38(5) shall apply to combustion of biofuel by aircraft operators.';

(11) in Article 72(1), the first subparagraph is replaced by the following:

'Total annual emissions of each of the greenhouse gases CO_2, N_2O and PFCs shall be reported as rounded tonnes of CO_2 or $CO_{2(e)}$. The total annual emissions of the installation shall be calculated as the sum of the rounded values for CO_2, N_2O and PFCs.';

(12) Annexes I and X are amended in accordance with Annex I to this Regulation;

(13) Annexes II, IV and VI are amended in accordance with Annex II to this Regulation.

Article 2

Correction to Implementing Regulation (EU) 2018/2066

In subsection B of section 8 of Annex IV to Implementing Regulation (EU) 2018/2066, 'Calculation Method B – Overvoltage Method' is corrected as follows:

(1) the formula 'C_2F_6 emissions [t] = CF_4 emissions × F_{CF2F6}' is replaced by 'C_2F_6 emissions [t] = CF_4 emissions × F_{C2F6}';

(2) the definition 'F_{CF2F6} = Weight fraction of C_2F_6 (t C_2F_6/t CF_4)' is replaced by 'F_{C2F6} = Weight fraction of C_2F_6 (t C_2F_6/t CF_4)'.

Article 3

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 1 shall apply from 1 January 2021.

However, points (1), (4) to (10) and (12) of Article 1 shall apply from 1 January 2022.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 December 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Annexes I and X to Implementing Regulation (EU) 2018/2066 are amended as follows:

(1) Annex I is amended as follows:

(a) in section 1, the following points (8) and (9) are added:

'(8) where applicable, a description of the procedure used to assess if biomass source streams comply with Article 38(5);

(9) where applicable, a description of the procedure used to determine biogas quantities based on purchase records in accordance with Article 39(4).';

(b) in point 2 of section 2, the following points (f) and (g) are added:

'(f) where applicable, a description of the procedure used to assess if biofuels comply with Article 38(5);

(g) where applicable, a description of the procedure used to determine biofuel quantities based on purchase records in accordance with Article 54(3).';

(2) Annex X is amended as follows:

(a) in point 6 of section 1, point (a) is replaced by the following:

'(a) the total emissions expressed as t $CO_{2(e)}$, including CO_2 from biomass source streams which do not comply with Article 38(5);';

(b) in point 8 of section 1, point (d) is replaced by the following:

'(d) emissions, amounts and energy content of biomass fuels and bioliquids combusted, expressed in t and TJ, and information whether such biomass fuels and bioliquids comply with Article 38(5).';

(c) section 2 is amended as follows:

(1) point 9 is replaced by the following:

'(9) Total CO_2 emissions in tonnes of CO_2 disaggregated by the Member State of departure and arrival, including CO_2 from biofuels which do not comply with Article 38(5);';

(2) point 12 is replaced by the following:

'(12) Memo-items:

(a) amount of biofuels used during the reporting year (in tonnes or m^3) listed per fuel type, and whether the biofuels comply with Article 38(5);

(b) the net calorific value of biofuels and alternative fuels;'.

ANNEX II

Annexes II, IV and VI to Implementing Regulation (EU) 2018/2066 are amended as follows:

(1) Annex II is amended as follows:

(a) in the first paragraph of section 2, the second sentence is replaced by the following:

'Where fuels or combustible materials which give rise to CO_2 emissions are used as a process input, section 4 of this Annex shall apply.';

(b) section 4 is replaced by the following:

'4. **DEFINITION OF TIERS FOR THE CALCULATION FACTORS FOR CO_2 PROCESS EMISSIONS**

For all CO_2 process emissions, in particular for emissions from the decomposition of carbonates and from process materials containing carbon other than in form of carbonates, including urea, coke and graphite, where they are monitored using the standard methodology in accordance with Article 24(2), the tiers defined in this section for the applicable calculation factors shall be applied.

In case of mixed materials which contain inorganic as well as organic forms of carbon, the operator may choose:

— to determine a total preliminary emission factor for the mixed material by analysing the total carbon content, and using a conversion factor and – if applicable – biomass fraction and net calorific value related to that total carbon content; or

— to determine the organic and inorganic contents separately and treat them as two separate source streams.

For emissions from the decomposition of carbonates, the operator may choose for each source stream one of the following methods:

(a) **Method A** (Input based): The emission factor, conversion factor and activity data are related to the amount of material input into the process.

(b) **Method B** (Output based): The emission factor, conversion factor and activity data are related to the amount of output from the process.

For other CO_2 process emissions, the operator shall apply only method A.

4.1. **Tiers for the emission factor using Method A**

Tier 1: The operator shall apply one of the following:

(a) the standard factors listed in Annex VI section 2 Table 2 in case of carbonate decomposition, or in Tables 1, 4 or 5 for other process materials;

(b) other constant values in accordance with point (e) of Article 31(1), where no applicable value is contained in Annex VI.

Tier 2: The operator shall apply a country specific emission factor in accordance with point (b) or (c) of Article 31(1), or values in accordance with point (d) of Article 31(1).

Tier 3: The operator shall determine the emission factor in accordance with Articles 32 to 35. Stoichiometric ratios as listed in section 2 of Annex VI shall be used to convert composition data into emission factors, where relevant.

4.2. **Tiers for the conversion factor using Method A**

Tier 1: A conversion factor of 1 shall be used.

Tier 2: Carbonates and other carbon leaving the process shall be considered by means of a conversion factor with a value between 0 and 1. The operator may assume complete conversion for one or several inputs and attribute unconverted materials or other carbon to the remaining inputs. The additional determination of relevant chemical parameters of the products shall be carried out in accordance with Articles 32 to 35.

4.3. **Tiers for the emission factor using Method B**

Tier 1: The operator shall apply one of the following:

(a) the standard factors listed in Annex VI section 2 Table 3.

(b) other constant values in accordance with point (e) of Article 31(1), where no applicable value is contained in Annex VI.

Tier 2: The operator shall apply a country specific emission factor in accordance with point (b) or (c) of Article 31(1), or values in accordance with point (d) of Article 31(1).

Tier 3: The operator shall determine the emission factor in accordance with Articles 32 to 35. Stoichiometric ratios referred to in Annex VI section 2 Table 3 shall be used to convert composition data into emission factors assuming that all of the relevant metal oxides have been derived from respective carbonates. For this purpose the operator shall take into account at least CaO and MgO, and shall provide evidence to the competent authority as to which further metal oxides relate to carbonates in the raw materials.

4.4. **Tiers for the conversion factor using Method B**

Tier 1: A conversion factor of 1 shall be used.

Tier 2: The amount of non-carbonate compounds of the relevant metals in the raw materials, including return dust or fly ash or other already calcined materials, shall be reflected by means of conversion factors with a value between 0 and 1 with a value of 1 corresponding to a full conversion of raw material carbonates into oxides. The additional determination of relevant chemical parameters of the process inputs shall be carried out in accordance with Articles 32 to 35.

4.5. **Tiers for the net calorific value (NCV)**

If relevant, the operator shall determine the net calorific value of the process material using the tiers defined in section 2.2 of this Annex. NCV is considered not relevant for *de minimis* source streams or where the material is not itself combustible without other fuels being added. If in doubt, the operator shall seek confirmation by the competent authority on whether NCV has to be monitored and reported.

4.6. **Tiers for the biomass fraction**

If relevant, the operator shall determine the biomass fraction of the carbon contained in the process material, using the tiers defined in section 2.4 of this Annex.';

(c) section 5 is deleted;

(2) Annex IV is amended as follows:

(a) in subsection C.2 of section 1, the first paragraph is replaced by the following:

'By way of derogation from section 4 of Annex II, process CO_2 emissions from the use of urea for scrubbing of the flue gas stream shall be calculated in accordance with Article 24(2) applying the following tiers.';

(b) in section 4, subsection B is replaced by the following:

'B. **Specific monitoring rules**

For the monitoring of emissions from metal ore roasting, sintering or pelletisation, the operator may choose to use a mass balance in accordance with Article 25 and section 3 of Annex II or the standard methodology in accordance with Article 24 and sections 2 and 4 of Annex II.';

(c) section 9 is amended as follows:

(1) subsection A is replaced by the following:

'A. **Scope**

The operator shall include at least the following potential sources of CO_2 emissions: calcination of limestone in the raw materials, conventional fossil kiln fuels, alternative fossil-based kiln fuels and raw materials, biomass kiln fuels (biomass wastes), non-kiln fuels, non-carbonate carbon content of limestone and shales and raw materials used for waste gas scrubbing.';

(2) in subsection B, the second paragraph is replaced by the following:

'CO_2 emissions related to dust removed from the process and non-carbonate carbon in the raw materials shall be added in accordance with subsections C and D of this section.';

(3) in subsection D, the second and third paragraphs are replaced by the following:

'By way of derogation from section 4 of Annex II, the following tier definitions for the emission factor shall apply:

Tier 1: The content of non-carbonate carbon in the relevant raw material shall be estimated using industry best practice guidelines.

Tier 2: The content of non-carbonate carbon in the relevant raw material shall be determined at least annually following the provisions of Article 32 to 35.

By way of derogation from section 4 of Annex II, the following tier definitions for the conversion factor shall apply:

Tier 1: A conversion factor of 1 shall be applied.

Tier 2: The conversion factor shall be calculated applying industry best practice.';

(d) section 10 is amended as follows:

(1) in subsection B, the first paragraph is replaced by the following:

'Emissions from combustion shall be monitored in accordance with section 1 of this Annex. Process emissions from raw materials shall be monitored in accordance with section 4 of Annex II. Carbonates of calcium and magnesium shall be always taken into account. Other carbonates and non-carbonate carbon in the raw material shall be taken into account, whenever they are relevant for emission calculation.';

(2) the following subsection C is added:

'C. **Emissions from non-carbonate carbon in raw materials**

The operator shall determine the emissions from non-carbonate carbon at least from limestone, shale or alternative raw materials in the kiln in accordance with Article 24(2).

By way of derogation from section 4 of Annex II, the following tier definitions for the emission factor shall apply:

Tier 1: The content of non-carbonate carbon in the relevant raw material shall be estimated using industry best practice guidelines.

Tier 2: The content of non-carbonate carbon in the relevant raw material shall be determined at least annually following the provisions of Article 32 to 35.

By way of derogation from section 4 of Annex II, the following tier definitions for the conversion factor shall apply:

Tier 1: A conversion factor of 1 shall be applied.

Tier 2: The conversion factor shall be calculated applying industry best practice.';

(e) in subsection B of section 11, the first paragraph is replaced by the following:

'Emissions from combustion, including flue gas scrubbing, shall be monitored in accordance with section 1 of this Annex. Process emissions from raw materials shall be monitored in accordance with section 4 of Annex II. Carbonates to be taken into account include at least $CaCO_3$, $MgCO_3$, Na_2CO_3, $NaHCO_3$, $BaCO_3$, Li_2CO_3, K_2CO_3, and $SrCO_3$. Only Method A shall be used. Emissions from other process materials including coke, graphite and coal dust shall be monitored in accordance with section 4 of Annex II.';

(f) section 12 is amended as follows:

(1) subsection A is replaced by the following:

'A. **Scope**

The operator shall include at least the following potential sources of CO_2 emissions: kiln fuels, calcination of limestone/dolomite and other carbonates in the raw material, limestone and other carbonates for reducing air pollutants and other flue gas cleaning, fossil/biomass additives used to induce porosity including polystyrol, residues from paper production or sawdust, non-carbonate carbon content in the clay and other raw materials.';

(2) in subsection B, the first paragraph is replaced by the following:

'Emissions from combustion including flue gas scrubbing shall be monitored in accordance with section 1 of this Annex. Process emissions from raw meal components and additives shall be monitored in accordance with section 4 of Annex II. For ceramics based on purified or synthetic clays the operator may use either Method A or Method B. For ceramic products based on unprocessed clays and whenever clays or additives with significant non-carbonate carbon content are used, the operator shall use Method A. Carbonates of calcium shall be always taken into account. Other carbonates and non-carbonate carbon in the raw material shall be taken into account, where they are relevant for emission calculation.';

(3) in Annex VI, Table 6 is replaced by the following:

'*Table 6*

Global warming potentials

Gas	Global warming potential
N_2O	265 t $CO_{2(e)}$/t N_2O
CF_4	6 630 t $CO_{2(e)}$/t CF_4
C_2F_6	11 100 t $CO_{2(e)}$/t C_2F_6'

COMMISSION IMPLEMENTING REGULATION (EU) 2020/2086

of 14 December 2020

amending Implementing Regulation (EU) 2020/532 as regards a derogation from Implementing Regulation (EU) No 809/2014 for checks by monitoring relating to aid applications for area-related aid schemes and payment claims for area-related support measures

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008 ([1]), and in particular points (a) and (b) of the first subparagraph of Article 62(2) thereof,

Whereas:

(1) Commission Implementing Regulation (EU) 2020/532 ([2]) contains certain derogations from, inter alia, Commission Implementing Regulation (EU) No 809/2014 ([3]) as regards certain administrative and on-the-spot checks applicable within the common agricultural policy.

(2) Certain elements of checks by monitoring implemented under Article 40a of Implementing Regulation (EU) No 809/2014 require visits in the field. However, due to movement restrictions put in place to address the pandemic of COVID-19, in the year 2020 Member States may not be in a position to carry out those checks as required by that Article. Therefore it is appropriate to provide for a derogation from certain provisions of that Article.

(3) Implementing Regulation (EU) 2020/532 should therefore be amended accordingly.

(4) As this Regulation provides for an additional derogation from Implementing Regulation (EU) No 809/2014 in respect of claim year 2020 due to the pandemic of COVID-19, it should enter into force on the day of its publication in the *Official Journal of the European Union* and apply retroactively from the same date as Implementing Regulation (EU) 2020/532.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Committee for Direct Payments and the Rural Development Committee,

HAS ADOPTED THIS REGULATION:

Article 1

In Implementing Regulation (EU) 2020/532, the following Article 4a is inserted:

'*Article 4a*

By way of derogation from the first sentence of point (c) of the first subparagraph of Article 40a(1) and point (b) of Article 40a(2) of Implementing Regulation (EU) No 809/2014, where due to the measures put in place to address the pandemic of COVID-19 Member States are not in a position to carry out all the checks that require field inspections, the following shall apply in respect of claim year 2020:

(a) the relevant checks relating to the eligibility criteria, commitments and other obligations shall be carried out for at least 3 % of the beneficiaries concerned;

(b) the verifications of tetrahydrocannabinol content in hemp shall be made for at least 10 % of the area.'

([1]) OJ L 347, 20.12.2013, p. 549.

([2]) Commission Implementing Regulation (EU) 2020/532 of 16 April 2020 derogating in respect of the year 2020 from Implementing Regulations (EU) No 809/2014, (EU) No 180/2014, (EU) No 181/2014, (EU) 2017/892, (EU) 2016/1150, (EU) 2018/274, (EU) 2017/39, (EU) 2015/1368 and (EU) 2016/1240 as regards certain administrative and on-the-spot checks applicable within the common agricultural policy (OJ L 119, 17.4.2020, p. 3).

([3]) Commission Implementing Regulation (EU) No 809/2014 of 17 July 2014 laying down rules for the application of Regulation (EU) No 1306/2013 of the European Parliament and of the Council with regard to the integrated administration and control system, rural development measures and cross compliance (OJ L 227, 31.7.2014, p. 69).

Article 2

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

It shall apply from 20 April 2020.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 December 2020.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2020/2087

of 14 December 2020

concerning the non-renewal of the approval of the active substance mancozeb, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ([1]), and in particular Article 20(1) and Article 78(2) thereof,

Whereas:

(1) Commission Directive 2005/72/EC ([2]) included mancozeb as an active substance in Annex I to Council Directive 91/414/EEC ([3]).

(2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([4]).

(3) The approval of the active substance mancozeb, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 January 2021.

(4) Applications for the renewal of the approval of mancozeb were submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ([5]) within the time period provided for in that Article.

(5) The applicants submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The applications were found to be complete by the rapporteur Member State.

(6) The rapporteur Member State prepared a renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority ('the Authority') and the Commission on 27 September 2017.

(7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the renewal assessment report to the applicants and to the Member States for comments and launched a public consultation on it. The Authority forwarded the comments received to the Commission.

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) Commission Directive 2005/72/EC of 21 October 2005 amending Council Directive 91/414/EEC to include chlorpyrifos, chlorpyrifos-methyl, mancozeb, maneb, and metiram as active substances (OJ L 279, 22.10.2005, p. 63).

([3]) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

([4]) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

([5]) Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

(8) On 20 June 2019, the Authority communicated to the Commission its conclusion ([6]) on whether mancozeb can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(9) Following the withdrawal of the United Kingdom from the EU on 31 January 2020, Greece agreed to take over the responsibility as rapporteur Member State.

(10) According to the provisions of Article 14 of Implementing Regulation (EU) No 844/2012, the Commission referred a draft renewal report to the Standing Committee on Plants, Animals, Food and Feed, for examination in March 2020. During the discussions in the Standing Committee, the new rapporteur Member State Greece informed that it considered as appropriate to evaluate data that in its view had been omitted by the earlier rapporteur Member State. Greece sent its evaluation to the Commission on 2 September 2020 in the form of an updated renewal assessment report. The evaluation was also made available to EFSA, the other Member States and the applicant.

(11) The draft renewal report was finalised by the Standing Committee on 23 October 2020.

(12) The Authority indentified certain specific concerns. In particular, it concluded that mancozeb has been classified as toxic for reproduction category 1B and that the new criteria to identify endocrine disrupting properties are met for humans and most likely for non-target organisms. In addition, it concluded that the non-dietary exposure estimates exceed the reference values for the representative uses in tomatoes, potatoes, cereals and grapevines. Therefore for the representative uses considered, non-dietary exposure to mancozeb also cannot be considered as negligible for the purposes of points 3.6.4 and 3.6.5 of Annex II to Regulation (EC) No 1107/2009. Given the concerns identified the derogation provided for in Article 4(7) to Regulation (EC) No 1107/2009 cannot apply.

(13) The Commission invited the applicants to submit their comments on the conclusion of the Authority and, in accordance with the third paragraph of Article 14(1) of Implementing Regulation (EU) No 844/2012, on the draft renewal report. The applicants submitted their comments which have been carefully examined.

(14) However, despite the arguments put forward by the applicants the concerns regarding the active substance could not be eliminated.

(15) Consequently, it has not been established with respect to one or more representative uses of at least one plant protection product that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate not to renew the approval of the active substance mancozeb.

(16) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(17) Member States should be given sufficient time to withdraw authorisations for plant protection products containing mancozeb.

(18) For plant protection products containing mancozeb, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should at the latest, expire on 4 January 2022.

(19) Commission Implementing Regulation (EU) 2019/2094 ([7]) extended until 31 January 2021 the period of approval of mancozeb in order to allow the renewal process to be completed before the expiry of the approval period of that substance. Given that a decision on the non-renewal of the approval has been taken ahead of that extended expiry date, this Regulation should apply as soon as possible.

(20) This Regulation does not prevent the submission of a further application for the approval of mancozeb pursuant to Article 7 of Regulation (EC) No 1107/2009.

(21) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

---

([6]) EFSA (European Food Safety Authority), 2019. Conclusion on the peer review of the pesticide risk assessment of the active substance mancozeb. *EFSA Journal* 2019;17(7):5755 DOI: 10.2903/j.efsa.2019.5755

([7]) Commission implementing Regulation (EU) 2019/2094 of 29 November 2019 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances benfluralin, dimoxystrobin, fluazinam, flutolanil, mancozeb, mecoprop-P, mepiquat, metiram, oxamyl and pyraclostrobin (OJ L 317, 9.12.2019, p. 102).

HAS ADOPTED THIS REGULATION:

Article 1

Non-renewal of approval of active substance

The approval of the active substance mancozeb is not renewed.

Article 2

Amendment to Implementing Regulation (EU) No 540/2011

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 114, on mancozeb, is deleted.

Article 3

Transitional measures

Member States shall withdraw authorisations for plant protection products containing mancozeb as an active substance at the latest by 4 July 2021.

Article 4

Grace period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall expire at the latest by 4 January 2022.

Article 5

Entry into force

This Regulation shall enter into force on twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 December 2020.

For the Commission
The President
Ursula VON DER LEYEN

DIRECTIVES

COMMISSION DIRECTIVE (EU) 2020/2088

of 11 December 2020

amending Annex II to Directive 2009/48/EC of the European Parliament and of the Council as regards the labelling of allergenic fragrances in toys

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys ([1]), and in particular point (b) of the first subparagraph of Article 46(1) thereof,

Whereas:

(1) Directive 2009/48/EC lays down a general obligation to list on the toy, on an affixed label, on the packaging or in an accompanying leaflet, if added to a toy, the names of 11 allergenic fragrances if the concentrations of those fragrances exceed 100 mg/kg in the toy or components thereof. Those allergenic fragrances are listed in the table in the third paragraph of point 11 of Part III of Annex II to that Directive.

(2) The Scientific Committee on Consumer Safety (SCCS), which assists the Commission as an independent risk assessment body in the area of cosmetic products, notes in its opinion of 26 and 27 June 2012 ([2]) that contact allergy to fragrances is a common, significant and relevant problem in Europe and that exposure to fragrances occurs from the use of other consumer products, such as toys. The SCCS also notes that, in recent years, it has become a trend to add fragrance chemicals to many types of consumer products, such as children's toys, which may contribute significantly to the fragrance exposure of the consumer by the dermal route. The SCCS adds that the consumer is exposed to fragrance substances from a wide variety of cosmetic products, other consumer products, pharmaceuticals and occupational exposures, and that all those exposures are of importance in the context of contact allergy as it is not the source of exposure that is critical, but the cumulative dose per unit area. In the opinion, a number of established contact allergens in humans are listed in Table 13-1.

(3) A survey of allergenic substances in products for children carried out by the Environmental Protection Agency in Denmark ([3]) shows the presence of allergenic fragrances in toys, namely modelling clays, slimes, a doll, a teddy bear, and rubber bands.

(4) The Expert Group on Toys Safety advises the Commission in the preparation of legislative proposals and policy initiatives in the area of toy safety. The mission of its subgroup on Chemicals in Toys (subgroup Chemicals) is to provide advice with regard to chemical substances which may be used in toys.

(5) The Expert Group on Toys Safety recalled, at its meeting on 13 September 2019 ([4]), that an allergenic substance, whether present in cosmetic products or in toys, is always allergenic. That so-called intrinsic property of the substance is independent from the use of the substance and is therefore present irrespective of whether the allergenic substance is used in cosmetics or in toys. Consequently, the Expert Group considered that an allergenic

([1]) OJ L 170, 30.6.2009, p. 1.

([2]) SCCS opinion on fragrance allergens in cosmetic products, 26 – 27 June 2012 (SCCS/1459/11). http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_102.pdf

([3]) Ministry of Environment and Food of Denmark – Environmental Protection Agency. Survey of allergenic substances in products targeted children – toys and cosmetic products. Survey of Chemical Substances in Consumer Products No 148, 2016. https://www2.mst.dk/Udgiv/publications/2016/08/978-87-93529-00-7.pdf

([4]) Minutes of the meeting of the Expert Group on Toys Safety of 13 September 2019 https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupMeeting&meetingId=17996

substance presenting a risk in cosmetic products could equally present a risk in toys. It therefore underlined the importance to take thorough account of the opinions of the SCCS and of its predecessor committees on allergenic fragrances in cosmetic products when regulating allergenic fragrances in toys.

(6) At the meeting of the subgroup Chemicals of 3 May 2018 ([5]), the majority of its members concluded that the established contact allergens in humans listed in Table 13-1 of the SCCS opinion of 26 and 27 June 2012 should be added to the list of allergenic fragrances that have to be listed on the toy, on an affixed label, on the packaging or in an accompanying leaflet, laid down in the table in the third paragraph of point 11 of Part III of Annex II to Directive 2009/48/EC.

(7) On 13 September 2019, the Expert Group on Toys Safety confirmed the conclusions of the subgroup Chemicals.

(8) At its meeting on 13 September 2019, the Expert Group on Toys Safety noted that entry 4 in the table in the third paragraph of point 11 of Part III of Annex II to Directive 2009/48/EC on citronellol, CAS number 106-22-9, covers only the mixture of the two enantiomeric forms of citronellol. The labelling requirements should however, according to the Expert Group, also cover the two individual enantiomeric forms listed as CAS numbers 1117-61-9 and 7540-51-4 in Table 13-1 of the SCCS opinion of 26 and 27 June 2012.

(9) In light of the SCCS opinion of 26 and 27 June 2012 and the recommendation of the Expert Group on Toys Safety of 13 September 2019, the allergenic fragrances listed in Table 13-1 of the SCCS opinion of 26 and 27 June 2012 should be subject to labelling requirements when present in toys. The fragrances that are not yet subject to a prohibition or labelling requirements laid down in Directive 2009/48/EC, should therefore be included in the table in the third paragraph of point 11 of Part III of Annex II to that Directive.

(10) Directive 2009/48/EC should therefore be amended accordingly.

(11) The measures provided for in this Directive are in accordance with the opinion of the Committee established under Article 47(1) of Directive 2009/48/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex II to Directive 2009/48/EC is amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by 4 July 2022 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from 5 July 2022.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

([5]) Minutes of the Meeting of the subgroup Chemicals of the Expert Group on Toy Safety of 3 May 2018. https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupMeetingDoc&docid=19025

Done at Brussels, 11 December 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In the third paragraph of point 11 of Part III of Annex II, the table is amended as follows:

(1) entry 4 is replaced by the following:

No	Name of the allergenic fragrance	CAS number
‘(4)	Citronellol	106-22-9; 1117-61-9; 7540-51-4’

(2) the following entries are added:

No	Name of the allergenic fragrance	CAS number
‘(12)	Acetylcedrene	32388-55-9
(13)	Amyl salicylate	2050-08-0
(14)	trans-Anethole	4180-23-8
(15)	Benzaldehyde	100-52-7
(16)	Camphor	76-22-2; 464-49-3
(17)	Carvone	99-49-0; 6485-40-1; 2244-16-8
(18)	beta-Caryophyllene (ox.)	87-44-5
(19)	Rose ketone-4 (Damascenone)	23696-85-7
(20)	alpha-Damascone (TMCHB)	43052-87-5; 23726-94-5
(21)	cis-beta-Damascone	23726-92-3
(22)	delta-Damascone	57378-68-4
(23)	Dimethylbenzyl carbinyl acetate (DMBCA)	151-05-3
(24)	Hexadecanolactone	109-29-5
(25)	Hexamethylindanopyran	1222-05-5
(26)	(DL)-Limonene	138-86-3
(27)	Linalyl acetate	115-95-7
(28)	Menthol	1490-04-6; 89-78-1; 2216-51-5
(29)	Methyl salicylate	119-36-8
(30)	3-methyl-5-(2,2,3-trimethyl-3-cyclopenten-1-yl)pent-4-en-2-ol	67801-20-1
(31)	alpha-Pinene	80-56-8
(32)	beta-Pinene	127-91-3
(33)	Propylidene phthalide	17369-59-4
(34)	Salicylaldehyde	90-02-8
(35)	alpha-Santalol	115-71-9
(36)	beta-Santalol	77-42-9
(37)	Sclareol	515-03-7
(38)	alpha-Terpineol	10482-56-1; 98-55-5
(39)	Terpineol (mixture of isomers)	8000-41-7
(40)	Terpinolene	586-62-9
(41)	Tetramethyl acetyloctahydro naphthalenes	54464-57-2; 54464-59-4; 68155-66-8; 68155-67-9

(42)	Trimethyl benzenepropanol (Majantol)	103694-68-4
(43)	Vanillin	121-33-5
(44)	Cananga odorata and Ylang-ylang oil	83863-30-3; 8006-81-3
(45)	Cedrus atlantica bark oil	92201-55-3; 8000-27-9
(46)	Cinnamomum cassia leaf oil	8007-80-5
(47)	Cinnamomum zeylanicum bark oil	84649-98-9
(48)	Citrus aurantium amara flower oil	8016-38-4
(49)	Citrus aurantium amara peel oil	72968-50-4
(50)	Citrus bergamia peel oil expressed	89957-91-5
(51)	Citrus limonum peel oil expressed	84929-31-7
(52)	Citrus sinensis (syn.: Aurantium dulcis) peel oil expressed	97766-30-8; 8028-48-6
(53)	Cymbopogon citratus/schoenanthus oils	89998-14-1; 8007-02-01; 89998-16-3
(54)	Eucalyptus spp. leaf oil	92502-70-0; 8000-48-4
(55)	Eugenia caryophyllus leaf/flower oil	8000-34-8
(56)	Jasminum grandiflorum/officinale	84776-64-7; 90045-94-6; 8022-96-6
(57)	Juniperus virginiana	8000-27-9; 85085-41-2
(58)	Laurus nobilis fruit oil	8007-48-5
(59)	Laurus nobilis leaf oil	8002-41-3
(60)	Laurus nobilis seed oil	84603-73-6
(61)	Lavandula hybrida	91722-69-9
(62)	Lavandula officinalis	84776-65-8
(63)	Mentha piperita	8006-90-4; 84082-70-2
(64)	Mentha spicata	84696-51-5
(65)	Narcissus spp.	Diverse, including 90064-25-8
(66)	Pelargonium graveolens	90082-51-2; 8000-46-2
(67)	Pinus mugo	90082-72-7
(68)	Pinus pumila	97676-05-6
(69)	Pogostemon cablin	8014-09-3; 84238-39-1
(70)	Rose flower oil (Rosa spp.)	Diverse, including 8007-01-0, 93334-48-6, 84696-47-9, 84604-12-6, 90106-38-0, 84604-13-7, 92347-25-6
(71)	Santalum album	84787-70-2; 8006-87-9
(72)	Turpentine (oil)	8006-64-2; 9005-90-7; 8052-14-0’

COMMISSION DIRECTIVE (EU) 2020/2089

of 11 December 2020

amending Annex II to Directive 2009/48/EC of the European Parliament and of the Council as regards the prohibition of allergenic fragrances in toys

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys ([1]), and in particular point (b) of the first subparagraph of Article 46(1) thereof,

Whereas:

(1) Directive 2009/48/EC lays down a general prohibition of 55 allergenic fragrances in toys, as listed in the table in the first paragraph of point 11 of Part III of Annex II to that Directive, in order to protect children from allergies that those fragrances can cause when used in toys.

(2) The Scientific Committee on Consumer Safety (SCCS), which assists the Commission as an independent risk assessment body in the area of cosmetic products, notes in its opinion of 26 and 27 June 2012 ([2]) that contact allergy to fragrances is a common, significant and relevant problem in Europe, and that exposure to fragrances occurs from the use of other consumer products, such as toys. The SCCS also notes that, in recent years, it has become a trend to add fragrance chemicals to many types of consumer products, such as children's toys, which may contribute significantly to the fragrance exposure of the consumer by the dermal route. The SCCS adds that the consumer is exposed to fragrance substances from a wide variety of cosmetic products, other consumer products, pharmaceuticals and occupational exposures, and that all those exposures are of importance in the context of contact allergy as it is not the source of exposure that is critical, but the cumulative dose per unit area.

(3) A survey of allergenic substances in products for children carried out by the Environmental Protection Agency in Denmark ([3]) shows the presence of allergenic fragrances in toys, namely modelling clays, slimes, a doll, a teddy bear, and rubber bands.

(4) The Expert Group on Toys Safety advises the Commission in the preparation of legislative proposals and policy initiatives in the area of toy safety. The mission of its subgroup on Chemicals in Toys (subgroup Chemicals) is to provide advice with regard to chemical substances which may be used in toys.

(5) The Expert Group on Toys Safety recalled, at its meeting on 13 September 2019 ([4]), that an allergenic substance, whether present in cosmetic products or in toys, is always allergenic. That so-called intrinsic property of the substance is independent from the use of the substance and is therefore present irrespective of whether the allergenic substance is used in cosmetics or in toys. Consequently, the Expert Group considered that an allergenic substance presenting a risk in cosmetic products could equally present a risk in toys. It therefore underlined the importance to take thorough account of the opinions of the SCCS and of its predecessor committees on allergenic fragrances in cosmetic products when regulating allergenic fragrances in toys.

([1]) OJ L 170, 30.6.2009, p. 1.

([2]) SCCS opinion on fragrance allergens in cosmetic products, 26 – 27 June 2012 (SCCS/1459/11). http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_102.pdf

([3]) Ministry of Environment and Food of Denmark – Environmental Protection Agency. Survey of allergenic substances in products targeted children – toys and cosmetic products. Survey of Chemical Substances in Consumer Products No 148, 2016. https://www2.mst.dk/Udgiv/publications/2016/08/978-87-93529-00-7.pdf

([4]) Minutes of the meeting of the Expert Group on Toys Safety of 13 September 2019 https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupMeeting&meetingId=17996

(6) Directive 2009/48/EC allows the Commission to prohibit or to require labelling of allergenic fragrances in toys. Contrary to Regulation (EC) No 1223/2009 of the European Parliament and of the Council ([5]), which regulates cosmetic products, it does not allow the Commission to set maximum limits for allergenic fragrances.

(7) In its opinion of 26 and 27 June 2012 the SCCS concluded that cosmetic products containing atranol or chloroatranol are not safe. The SCCS thus confirmed the opinion of the Scientific Committee on Consumer Products (SCCP) of 7 December 2004 ([6]) that atranol and chloroatranol should not be present in consumer products. The subgroup Chemicals therefore recommended, at its meeting on 3 May 2018 ([7]), to prohibit the use of atranol and chloroatranol in toys, by adding them to the table in the first paragraph of point 11 of Part III of Annex II to Directive 2009/48/EC.

(8) In its opinion of December 1999 ([8]), the Scientific Committee on Cosmetic Products and non-food Products intended for Consumers (SCCNFP), which was a predecessor of the SCCS, included methyl heptine carbonate among the fragrance chemicals less frequently reported as contact allergens. On the basis of that opinion, methyl heptine carbonate was included among the allergenic fragrances that have to be listed on the toy, on an affixed label, on the packaging or in an accompanying leaflet, in accordance with the third paragraph of point 11 of Part III of Annex II to Directive 2009/48/EC. In its opinion of 25 September 2001 ([9]), the SCCNFP recommended that the level of methyl heptine carbonate in finished cosmetic products should not exceed 0,01 %.

(9) Considering the above, and in particular the SCCS opinion concluding that cosmetic products containing atranol or chloroatranol are not safe, the SCCP opinion that atranol and chloroatranol should not be present in consumer products and the SCCNFP opinion that methyl heptine carbonate should not exceed 0,01 % in cosmetic products, the Expert Group on Toys Safety recommended, at its meeting on 13 September 2019, to prohibit the use of atranol, chloroatranol and methyl heptine carbonate in toys.

(10) In light of the opinions of the SCCS, the SCCP and the SCCNFP, and of the recommendation of the Expert Group on Toys Safety the use of atranol, chloroatranol and methyl heptine carbonate in toys should be prohibited.

(11) Directive 2009/48/EC should therefore be amended accordingly.

(12) The measures provided for in this Directive are in accordance with the opinion of the Committee established under Article 47(1) of Directive 2009/48/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex II to Directive 2009/48/EC is amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by 4 July 2022 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from 5 July 2022.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

([5]) Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).

([6]) SCCP opinion on atranol and chloroatranol present in natural extracts (e.g. oak moss and tree moss extract), 7 December 2004 (SCCP/00847/04).
https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_006.pdf

([7]) Minutes of the Meeting of the Subgroup 'Chemicals' of the Expert Group on Toy Safety of 3 May 2018.
https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupMeetingDoc&docid=19025

([8]) Opinion concerning Fragrance Allergy in Consumers – A review of the problem. Analysis of the need for appropriate consumer information and identification of consumer allergens, 8 December 1999 (SCCNFP/0017/98 Final), Table 6b, p. 23.
https://ec.europa.eu/health/ph_risk/committees/sccp/documents/out98_en.pdf

([9]) Opinion concerning An initial List of Perfumery Materials which must not form Part of Cosmetic Products except subject to the Restrictions and Conditions laid down, 25 September 2001 (SCCNFP/0392/00 final), p. 8.
https://ec.europa.eu/health/ph_risk/committees/sccp/documents/out150_en.pdf

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 11 December 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Part III of Annex II, point 11 is amended as follows:

(1) in the first paragraph, in the table, the following entries are added:

No	Name of the allergenic fragrance	CAS number
‘(56)	Atranol (2,6-Dihydroxy-4-methyl-benzaldehyde)	526-37-4
(57)	Chloroatranol (3-Chloro-2,6-Dihydroxy-4-methyl-benzaldehyde)	57074-21-2
(58)	Methyl heptine carbonate	111-12-6’

(2) in the third paragraph, in the table, entry 10 is deleted.

DECISIONS

DECISION (EU) 2020/2090 OF THE EUROPEAN CENTRAL BANK

of 4 December 2020

amending Decision ECB/2013/10 on the denominations, specifications, reproduction, exchange and withdrawal of euro banknotes (ECB/2020/60)

THE GOVERNING COUNCIL OF THE EUROPEAN CENTRAL BANK,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 128(1) thereof,

Having regard to the Statute of the European System of Central Banks and of the European Central Bank, and in particular Article 16 thereof,

Whereas:

(1) There has been an increase in the number of reproductions of euro banknotes withdrawn from circulation which the general public might risk mistaking for genuine euro banknotes, despite the fact that some of these reproductions bear small or not easily detectable indications that they are 'copies', 'not legal tender' or should 'be used only for movies or props', as they have the optical appearance of euro banknotes and imitate certain banknote security features. These reproductions are mainly offered and purchased via online market places or websites. Reproductions which the general public might mistake for genuine banknotes are unlawful pursuant to Decision ECB/2013/10 ([1]). It is therefore important to enact measures to reduce and eventually stop their further dissemination. In particular, a clearer prohibition of unlawful activities increases legal certainty. At the same time, it is important to have the possibility to exempt activities regarding certain reproductions, if the Eurosystem deems that the general public cannot mistake them for genuine euro banknotes.

(2) Therefore, Decision ECB/2013/10 should be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Amendment

Article 2 of Decision ECB/2013/10 is replaced by the following:

'*Article 2*

Reproduction rules for euro banknotes

1. "Reproduction" shall mean any tangible or intangible image that uses all or part of a euro banknote as specified in Article 1, or parts of its individual design elements such as, inter alia, colour, dimensions and use of letters or symbols, which image may resemble or give the general impression of a genuine euro banknote, irrespective of:

(a) the size of the image; or

(b) the material(s) or technique(s) used to produce it; or

(c) whether or not elements of the design of the euro banknote, such as the letters or symbols, have been altered or added to.

([1]) Decision ECB/2013/10 of 19 April 2013 on the denominations, specifications, reproduction, exchange and withdrawal of euro banknotes (OJ L 118, 30.4.2013, p. 37).

2. Unless the ECB or an NCB agrees to an exemption as set out in paragraph 5, reproductions which do not comply with the criteria set out in paragraph 3 shall be deemed unlawful and their production, possession, transportation, dissemination, selling, promotion, import into the Union and use or attempted use for transactions prohibited.

3. Reproductions complying with the following criteria shall be deemed lawful, since there is no risk that the general public might mistake them for genuine euro banknotes:

(a) one-sided reproductions of a euro banknote as specified in Article 1, provided that the size of the reproduction is equal to or greater than 125 % of both the length and width, or equal to or less than 75 % of both the length and the width of the respective euro banknote as specified in Article 1; or

(b) two-sided reproductions of a euro banknote as specified in Article 1, provided that the size of the reproduction is equal to or greater than 200 % of both the length and width or equal to or less than 50 % of both the length and width of the respective euro banknote as specified in Article 1; or

(c) reproductions of individual design elements of a euro banknote as specified in Article 1, provided that such a design element is not depicted on a background resembling a banknote; or

(d) one-sided reproductions depicting a part of the front side or reverse side of a euro banknote, provided that such a part is smaller than one third of the original front side or reverse side of the euro banknote as specified in Article 1; or

(e) reproductions made of a material clearly different from paper, which looks and feels distinctly different from the material used for banknotes; or

(f) intangible reproductions made available electronically on websites, by wire or wireless means or by any other means that allow members of the public to access these intangible reproductions from a place and at a time individually chosen by them, provided that:

— the word SPECIMEN (sample) (or its equivalent in another official language of the European Union) is incorporated diagonally across the reproduction in Arial font or a font similar to Arial font,

— the resolution of the electronic reproduction in its 100 % size does not exceed 72 dots per inch (dpi),

— the length of the word SPECIMEN (or its equivalent in another official language of the European Union) is at least 75 % of the length of the reproduction,

— the height of the word SPECIMEN (or its equivalent in another official language of the European Union) is at least 15 % of the width of the reproduction, and

— the word SPECIMEN (or its equivalent in another official language of the European Union) is displayed in a non-transparent (opaque) colour contrasting with the dominant colour of the respective euro banknote as specified in Article 1.

5. Exceptionally the ECB or the relevant NCB, as applicable, may, upon receiving a written request, consent to exempt a reproduction that does not comply with the criteria of paragraph 3 from the prohibition set out in paragraph 2, if the ECB or the relevant NCB considers that the reproduction cannot be mistaken by the general public for a genuine euro banknote as specified in Article 1. Where a reproduction is produced in the territory of only one Member State whose currency is the euro, such requests for an exemption shall be addressed to the NCB of that Member State. In all other cases, such requests shall be addressed to the ECB.

6. Reproduction rules for euro banknotes also apply to euro banknotes that have been withdrawn or have lost their legal tender status under this Decision.'

Article 2

Final provisions

This Decision shall enter into force on the twentieth day following its publication in the *Official Journal of the European Union*.

Done at Frankfurt am Main, 4 December 2020.

The President of the ECB
Christine LAGARDE

GUIDELINES

GUIDELINE (EU) 2020/2091 OF THE EUROPEAN CENTRAL BANK

of 4 December 2020

amending Guideline ECB/2003/5 on the enforcement of measures to counter non-compliant reproductions of euro banknotes and on the exchange and withdrawal of euro banknotes (ECB/2020/61)

THE GOVERNING COUNCIL OF THE EUROPEAN CENTRAL BANK,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 128(1) thereof,

Having regard to the Statute of the European System of Central Banks and of the European Central Bank, and in particular Articles 12.1 and 14.3 and Article 16 thereof,

Whereas:

(1) There has been an increase in the number of reproductions of euro banknotes withdrawn from circulation which the general public might risk mistaking for genuine euro banknotes, despite the fact that some of these reproductions bear small or not easily detectable indications that they are 'copies', 'not legal tender' or should 'be used only for movies or props', as they have the optical appearance of euro banknotes and imitate certain banknote security features. These reproductions are mainly offered and purchased via online market places or websites. Reproductions which the general public might mistake for genuine banknotes are unlawful pursuant to Guideline ECB/2003/5 ([1]). It is therefore important to enact measures to reduce and eventually stop their further dissemination complementing the existing measures the Eurosystem has at its disposal, including infringement proceedings which may result in sanctions pursuant to Council Regulation (EC) No 2532/98 ([2]).

(2) Since the introduction of euro banknotes, Eurosystem members have exchanged views on whether certain reproductions are lawful or unlawful to ensure harmonised interpretations throughout the euro area. However, to deal with possible future requests for exemptions for types of reproductions that cannot be assessed in the light of the established practice, a procedure to ensure harmonised interpretations in such situations needs to be put in place.

(3) Therefore, Guideline ECB/2003/5 should be amended accordingly,

HAS ADOPTED THIS GUIDELINE:

Article 1

Amendments

Guideline ECB/2003/5 is amended as follows:

(1) Article 1 is replaced by the following:

'*Article 1*

Definitions

For the purposes of this Guideline:

1. a "non-compliant reproduction" means any reproduction referred to in Article 2(1) of Decision ECB/2013/10 of the European Central Bank (*) that:

([1]) Guideline ECB/2003/5 of 20 March 2003 on the enforcement of measures to counter non-compliant reproductions of euro banknotes and on the exchange and withdrawal of euro banknotes (OJ L 78, 25.3.2003, p. 20).

([2]) Council Regulation (EC) No 2532/98 of 23 November 1998 concerning the powers of the European Central Bank to impose sanctions (OJ L 318, 27.11.1998, p. 4).

(a) does not comply with the criteria set out in Article 2(3) of Decision ECB/2013/10 and is not exempted by the ECB or the relevant NCB under Article 2(5) of Decision ECB/2013/10; or

(b) infringes the ECB's copyright on euro banknotes for instance by adversely affecting the standing of euro banknotes;

2. a "non-compliant activity" means the production, possession, transportation, dissemination, selling, promotion, import into the Union and use or attempted use for transactions of non-compliant reproductions.

(*) Decision ECB/2013/10 of 19 April 2013 on the denominations, specifications, reproduction, exchange and withdrawal of euro banknotes (OJ L 118, 30.4.2013, p. 37).';

(2) Article 2 is amended as follows:

(a) the title of Article 2 is replaced by the following:

'Enforcement of measures to counter non-compliant activities';

(b) paragraph 1 is replaced by the following:

'1. Where an NCB becomes aware of a non-compliant activity engaged in its national territory, it shall, by means of a standardised communication provided by the ECB, order the non-compliant party to stop engaging in one or more of the relevant non-compliant activities, and shall, where deemed appropriate, order the party in possession of the non-compliant reproduction to hand over the non-compliant reproduction.';

(c) the following paragraphs 1a, 1b and 1c are inserted:

'1a. Where an NCB becomes aware of the engagement in a non-compliant activity, whether direct or indirect, including through electronic form on websites with the relevant national url domains, by wire or wireless means, or by any other means that allow members of the public to access the non-compliant reproduction from a place and at a time individually chosen by them, it shall notify the ECB without delay. The NCB shall also, using a standardised template provided by the ECB, order the non-compliant party to stop engaging in the non-compliant activity. The ECB shall then take all possible steps to remove the non-compliant reproduction from the electronic location.

1b. The ECB may also order the non-compliant party to stop engaging in one or more of the relevant non-compliant activities in the territory of more than one Member State and outside the Union. Where deemed appropriate, the ECB shall order the party in possession of the non-compliant reproduction to hand over the non-compliant reproduction.

1c. Prior to taking any of the measures referred to in this Article, an NCB shall inform the ECB and the ECB shall coordinate the measures to be taken so that the NCB or the ECB, as applicable, is acting within its required competence when taking any measures.';

(d) paragraph 3 is replaced by the following:

'3. A subsequent decision to initiate an infringement procedure on the basis of Article 3(1) of Council Regulation (EC) No 2532/98 (*) which may result in sanctions being imposed in accordance with that Regulation shall be taken by either the Executive Board of the ECB or the relevant NCB. Prior to taking such decision, the ECB and the relevant NCB shall consult each other and the NCB shall inform the ECB whether a separate infringement procedure has been, or alternatively can be, initiated under national criminal law, and moreover, whether there is any other appropriate legal basis for action against the non-compliant activity, such as copyright law. Where an infringement procedure has already been initiated, or alternatively is to be initiated under national criminal law, or there is any other appropriate legal basis for action against the non-compliant activity, no infringement procedure under Regulation (EC) No 2532/98 shall be initiated.

(*) Council Regulation (EC) No 2532/98 of 23 November 1998 concerning the powers of the European Central Bank to impose sanctions (OJ L 318, 27.11.1998, p. 4).';

(e) paragraph 5 is replaced by the following:

'5. The ECB shall take the steps described in this Article acting on its own if:

(a) the origin of the non-compliant activity cannot reasonably be established; or

(b) the non-compliant activity has been or will be engaged in within the territories of several participating Member States; or

(c) the non-compliant activity has been or will be engaged in outside the territories of the participating Member States.';

(3) Article 3 is replaced by the following:

'*Article 3*

Requests for an exemption for reproductions

1. All requests for an exemption in accordance with Article 2(5) of Decision ECB/2013/10 shall be dealt with:

(a) by the respective NCB, on the ECB's behalf, if the reproductions have only been or will only be produced in the territory of its Member State; or

(b) by the ECB in all other cases described in Article 2(5) of Decision ECB/2013/10.

2. If an NCB receives a request for an exemption of a novel kind, the NCB shall inform the ECB of the request and its intention either to grant or to deny an exemption. Should the ECB's and the NCB's views in this respect differ from each other, the Executive Board shall decide. In reaching its decision, the Executive Board shall take into account the views of the Banknote Committee and the Legal Committee, in particular any views expressed concerning the individual situation of the Member State in question subject to views expressed on the implications of the decision for the entire euro area. The ECB shall collect the data on the requests received by it (whether or not addressed to it) and the responses to those requests and inform the NCBs thereof. The ECB may also publish the consolidated data from time to time.'.

Article 2

Taking effect

This Guideline shall take effect on the day of its notification to the national central banks of the Member States whose currency is the euro.

Article 3

Addressees

This Guideline is addressed to all Eurosystem central banks.

Done at Frankfurt am Main, 4 December 2020.

For the Governing Council of the ECB
The President of the ECB
Christine LAGARDE

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)



Publications Office
of the European Union
L-2985 Luxembourg
LUXEMBOURG

EN